THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

In re Tecfidera Antitrust Litigation This Document Relates to: All Actions	Case No. 1:24-cv-07387 Hon. April M. Perry DEMAND FOR JURY TRIAL

CONSOLIDATED SECOND AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

Plaintiffs Local No. 1 Health Fund, Mayor and City Council of Baltimore, Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund, New York State Teamsters Council Health and Hospital Fund, UFCW Local 1500 Welfare Fund, and Jacksonville Police Officers and Fire Fighters Health Insurance Trust (together, "Plaintiffs"), are health-benefit plans, or the sponsors of such plans, that provide healthcare benefits to their members. Plaintiffs, on behalf of themselves and all others similarly situated, based upon personal knowledge, the investigation of counsel, and upon information and belief, file this Consolidated Second Amended Class Action Complaint ("Complaint") and allege as follows against Defendant Biogen Inc. ("Biogen"):

I. NATURE OF THE ACTION

1. This civil antitrust and RICO action seeks damages and other relief arising out of Defendant Biogen Inc.'s unlawful scheme to impair competition from generic versions of its brand-name prescription drug Tecfidera. Tecfidera is used to treat multiple sclerosis ("MS").

2. The Food and Drug Administration ("FDA") approved Tecfidera in 2013, and it quickly reached blockbuster status, achieving $3.5 billion in U.S. sales by 2015 and remaining in the range of $3.3 to $3.8 billion annually through 2020.

3. These sales reflected Tecfidera's extremely high sales price, which rose to nearly $90,000 per patient per year. Biogen's manufacturing costs were less than $300 per patient per year—it sold Tecfidera at 300 times its costs. Biogen was able to reap these monopoly profits because it had a patent on Tecfidera.

4. But that patent was very weak. Beginning in 2017—as soon as legally permissible—numerous generic-drug manufacturers began challenging the validity of the Tecfidera patent. Biogen knew that once it lost those patent lawsuits its Tecfidera sales and profits would fall off the "patent cliff." Generic versions would quickly take 90% or more of the unit sales

and would be sold at a small fraction of Biogen's price. This competition would save billions of dollars for Plaintiffs and other purchasers of Tecfidera.

5. To forestall this competition and the consequent loss of its sales, Biogen crafted a multi-part scheme to impair competition from generic Tecfidera. The scheme included entering into unlawful restraints of trade with each of five of the nation's largest pharmacy benefit managers—Caremark Rx, LLC, OptumRx, Inc., Express Scripts, Inc., Humana Pharmacy Solutions, Inc., and MedImpact Healthcare Systems, Inc. Collectively, these five Pharmacy Benefit Managers ("PBMs") control the pharmacy benefits for more than 90% of Americans. Pursuant to these exclusionary agreements, Biogen paid the PBMs to manipulate the placement of generic Tecfidera on their formularies—the lists that identify which drugs are covered and establish the applicable patient copayments and coinsurance.

6. Biogen paid each of these five PBMs (and others) to refrain from advantaging generic Tecfidera over branded Tecfidera on their formularies, thereby foreclosing them from a substantial portion of the market. Biogen labeled these payments as "rebates" or "fees." In reality they were kickbacks to the PBMs for helping to insulate Tecfidera from lower-priced generic competition.

7. While the PBMs passed some of the rebates (none of the fees) on to some of their health plan clients, the rebates were not legitimate and honest ways for Biogen to compete with generic Tecfidera on price. For example, in 2022 generic Tecfidera was selling at a 93% discount off the list price of branded Tecfidera. In contrast, Biogen's average rebates and fees on branded Tecfidera were less than 28% off the list price. Biogen's rebates and fees were payments *to the PBMs* in exchange for excluding the generics, not price reductions to the health plans that, even if fully passed on to them, would have produced savings anywhere near what the generics offered.

8. Biogen's bought-and-paid-for market manipulations substantially muted the competition from generic Tecfidera. Putting generic Tecfidera on the same (or worse) formulary tier as branded Tecfidera resulted in insureds paying the same (or higher) copayment for the generic as for the brand. This eliminated the price signals that otherwise would guide insureds to properly weigh the relative costs of the drugs when choosing which one to buy. And for a substantial portion of insureds, equalizing the copayments for brand Tecfidera and generic Tecfidera altogether prohibited the pharmacy from dispensing the generic under state law.

9. The equal (or higher) copayments for generic Tecfidera made it appear to the insureds that generic Tecfidera cost the same as, or more than, brand Tecfidera. The opposite was true. The vast majority of the products' cost was paid by Plaintiffs and other health plans. But Biogen's payments in exchange for the same or better tier placement ensured that those who chose whether to buy the brand or the generic—the insureds—were deceived about, and sheltered from, the products' relative *total* costs.

10. Biogen also paid the PBMs to impose on generic Tecfidera the same dispensing restrictions that they imposed on Tecfidera. Most PBMs had previously designated Tecfidera as a "specialty drug." They gave branded Tecfidera that designation not based on any medical necessity, special handling requirements, or the like, but based on its astronomical price. Biogen paid the PBMs to treat generic Tecfidera the same as or less favorably than Tecfidera. As part of that corrupt bargain, the Co-Conspirator PBMs had to also designate generic Tecfidera as a specialty drug, even though the generics were available at wholesale prices a small fraction of those of the brand.

11. Biogen required that the falsely designated generic be dispensed only through a small number of "specialty pharmacies," which were owned by the Co-Conspirator PBMs. Biogen

knew and intended that causing generic Tecfidera to be distributed through this small set of specialty pharmacies would substantially depress the sales of generic Tecfidera. Doing so kept generic Tecfidera's price to health plans and other purchasers outrageously high. The PBM-affiliated specialty pharmacies bought generic Tecfidera from the manufacturers for as little as $180 for a 30-day supply; they sold it to the health plans and their insureds for as much as $3,857 for a 30-day supply—more than a 2,000% markup.

12. Biogen's requirement that the PBMs impose the same dispensing restrictions on generic Tecfidera also caused the generics to be subject to step edits and prior authorizations—red tape designed to inhibit insureds from buying the generic. Biogen thus arranged for a massively less expensive generic drug to be treated as if it were one of the very highest-priced branded drugs. Those restrictions, like the specialty-drug designations, substantially delayed and impaired the uptake of generic Tecfidera.

13. To minimize the chance that any portion of the market could work unimpaired, Biogen also provided "coupons" that insureds could use to eliminate their copayment or coinsurance when they filled their prescription with branded Tecfidera. Like the formulary-placement tactic, this anticompetitive tool also obscured the price signals that the insureds received. The coupons made it appear to the insureds that generic Tecfidera cost more than brand Tecfidera. Again, Biogen's anticompetitive tactic gave the insureds false price signals about the products' relative *total* costs.

14. These four Biogen tactics—payments to distort formulary placement, payments conditioned on specialty-drug designations, payments to impose step edits and prior authorizations, and providing copayment and coinsurance coupons—worked individually and

holistically to impair competition from generic Tecfidera. Collectively, these Biogen tactics affected the purchases of well over 75% of all insureds.

15. Piling injury on injury, this impaired competition gave Biogen the time it needed to switch a large portion of the market from Tecfidera to a "next generation" version of Tecfidera, called Vumerity. That market switch significantly and permanently impaired generic competition, and the harms from it continue today.

16. Vumerity and Tecfidera create the same active drug substance—monomethyl fumarate—in the body. They each deliver the same bioequivalent exposure to monomethyl fumarate and therefore have the same effectiveness and safety profile. In fact, Biogen received expedited FDA approval of Vumerity by proving that it was bioequivalent to Tecfidera, i.e., that its active ingredient is present in the patient's blood to the same extent and for the same amount of time.

17. Vumerity was different from Tecfidera not in a medically important way, but in an *economically* important way. When filling a prescription written for Vumerity, pharmacists could not automatically substitute generic Tecfidera. *See* Section IV(B) below. So Biogen orchestrated an anticompetitive scheme to get doctors to switch their prescribing from Tecfidera to Vumerity.

18. As noted, Biogen paid the PBMs and used patient coupons to delay and impair the uptake of generic Tecfidera. The weakened competition from generic Tecfidera gave Biogen the time and scope it needed to implement the scheme to switch prescriptions from Tecfidera to Vumerity.

19. That scheme had many anticompetitive elements. Among other things, Biogen concocted the false claim that Vumerity is medically superior to Tecfidera. It isn't. Then Biogen

pervasively marketed that false claim to doctors, patients, and other industry participants, even making its sales representatives' compensation depend on getting the prescriptions switched.

20. Biogen also paid the PBMs to place generic Tecfidera on the same formulary tier as Vumerity, eliminating any financial incentive for doctors or patients to resist the switch from Tecfidera to Vumerity. To further interfere with accurate price signals, Biogen gave coupons to insureds who bought Vumerity, making Vumerity falsely appear to be less costly than generic Tecfidera. Biogen tied rebates and fees on Tecfidera to the PBMs' giving better formulary placement of Vumerity. And Biogen also directly reduced the supply of generic Tecfidera, causing a major supplier of generic Tecfidera to exit the market altogether.

21. Biogen's top management made clear the comprehensive scope of the scheme to switch the market to Vumerity. In July 2020 Biogen's CEO admitted that

> "since the focus now is on VUMERITY not on [Tecfidera], I can tell you that all levels [at Biogen] are aligned, at the payer level, at the patient services level, at the salesforce level—including incentive schemes—to shape their behavior, at the medical affairs level. So, the organization is absolutely aligned and focused on all of those levers."

22. Biogen's scheme had the intended effect. With unimpaired generic competition, pharmacies would have dispensed about 2.2 million units of generic Tecfidera every month within 10 months of the generic becoming available; instead they were dispensing about a third of that amount.

23. Correspondingly, pharmacies would have dispensed fewer than 300,000 units of branded Tecfidera and Vumerity (combined) every month; instead they dispensed more than five times that amount. Even today—five years after generic entry—Biogen's unlawful conduct has suppressed generic Tecfidera sales far below the competitive level, while artificially inflating the sales of high-priced Tecfidera/Vumerity.

24. Moreover, focusing exclusively on the unit sales of generic Tecfidera does not capture the full extent of the anticompetitive harm that Biogen has inflicted on purchasers. Biogen's agreements with the PBMs to designate generic Tecfidera as a specialty drug has resulted in astronomical prices for 60% or more of the "generic" units. *Real* generic Tecfidera—sold at competitive, non-specialty prices—accounted for less than 17% of the market unit sales in 2021, for example, instead of the 90+% that free and fair competition would have delivered.

25. These supracompetitive prices on Tecfidera, Vumerity, and generic Tecfidera place a notable financial strain on health plans, because they directly shoulder the burden of high-cost prescription drugs. Smaller businesses feel this strain most acutely; the high cost of even a single specialty medication can represent a significant proportion of their overall health-benefit costs.

26. Together with its PBM Co-Conspirators, Biogen has unlawfully (1) restrained, suppressed, and eliminated competition in the market for Vumerity, Tecfidera, and their generic equivalents; (2) maintained monopoly and supracompetitive prices for those drug products; and (3) prevented Plaintiffs from purchasing the drugs in a competitive market, robbing them of billions of dollars in the aggregate.

27. Further, Biogen paid the Co-Conspirator PBMs to suppress the uptake of generic Tecfidera with the intent of improperly influencing or corrupting the PBMs' process of using formularies to promote low-cost products over higher-cost alternatives for the benefit of the PBMs' health plan clients. Biogen's payments were illegal commercial bribes designed to reduce competition. And, as to health plans governed by the Employee Retirement Income Security Act ("ERISA"), Biogen and the Co-Conspirator PBMs repeatedly violated 18 U.S.C. § 1954. That statute prohibits the payment of bribes, kickbacks, or other conflict-of-interest payments to organizations that provide services to ERISA plans, and the receipt of such payments by

organizations that provide services to ERISA plans, with the intent to influence ERISA plans' actions, decisions, or duties. In addition to the antitrust violations described in this Complaint, Biogen and its Co-Conspirators' conduct violated Section 1962(c) of the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), as explained in Count VI below.

II. PARTIES AND BIOGEN'S CO-CONSPIRATORS

A. Plaintiffs

28. Plaintiff Local No. 1 Health Fund ("Local 1 Health Fund") is a multi-employer welfare plan whose stated purpose is to provide health benefits to eligible members and dependents. Local 1 Health Fund is maintained and administered in accordance with and pursuant to the provisions of § 302(c)(5) of the National Labor Relations Act. Local 1 Health Fund's principal place of business is located at 1431 Opus Place, Suite 350, Downers Grove, Illinois. It is a self-insured health and welfare benefit plan, and it purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

29. During the Class Period, Local 1 Health Fund and other Class members purchased substantial amounts of generic Tecfidera, Tecfidera and Vumerity in, among other jurisdictions, Illinois, other than for resale. Local 1 Health Fund bought these products directly from Biogen's co-conspiring specialty pharmacies (such as Accredo Health Group, Inc. ("Accredo") and CVS Specialty Pharmacy). Local 1 Health Fund and other Class members paid more for Tecfidera, Vumerity, and generic Tecfidera than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, Local 1 Health Fund and the other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera and Vumerity, and would have paid less for generic Tecfidera.

30. During the Class Period, Local 1 Health Fund hired Express Scripts and CVS Caremark as its PBMs to manage its pharmacy benefit, which included formulary management services. During the Class Period, Express Scripts' formulary treated generic Tecfidera the same as Tecfidera so that insureds paid the same copay amount for generic Tecfidera and Tecfidera, and placed other formulary restrictions on generic Tecfidera. Similarly, CVS Caremark's formulary treated generic Tecfidera the same as Vumerity so that insureds paid the same copay amount for generic Tecfidera and Vumerity, and placed other formulary restrictions on generic Tecfidera. Among other things, both PBMs restricted distribution of generic Tecfidera to specialty pharmacies, charging speciality pharmacy prices.

31. Plaintiff the Mayor and City Council of Baltimore ("City of Baltimore") is a municipality located in Baltimore, Maryland. The City of Baltimore provides health benefits to eligible employees, retirees, and their beneficiaries. The City of Baltimore provides self-insured prescription drug coverage, and it purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

32. During the Class Period, the City of Baltimore purchased substantial amounts of Tecfidera, generic Tecfidera, and/or Vumerity in, among other jurisdictions, Florida, Maryland, and Pennsylvania, for the personal use of its members and beneficiaries, other than for resale. The City of Baltimore bought these products directly from Biogen's co-conspiring specialty pharmacies (such as CVS Specialty Pharmacy) and indirectly from others. The City of Baltimore and other Class members paid more for Vumerity, Tecfidera, or its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, the City

of Baltimore and the other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera or Vumerity, and would have paid less for generic Tecfidera.

33. During the Class Period, the City of Baltimore Fund hired CVS Caremark as its PBM to manage its pharmacy benefit, which included formulary management services. During the Class Period, that PBM's formulary treated generic Tecfidera the same as Vumerity so that insureds paid the same copay amount for generic Tecfidera as Vumerity, and placed other formulary restrictions on generic Tecfidera. Among other things, that PBM restricted distribution of generic Tecfidera to specialty pharmacies, charging generic specialty pharmacy prices.

34. Plaintiffs Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund (collectively "Teamsters Local 237") are two related health and welfare benefit plans headquartered and with a principal place of business in New York, New York. Teamsters Local 237 administer the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. Teamsters Local 237 provide health and welfare benefits to active and retired members and participants who reside in numerous locations in the United States. They are self-insured health and welfare benefit plans, and they purchase, pay and/or provide reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

35. During the Class Period, Teamsters Local 237 purchased substantial amounts of Tecfidera, generic Tecfidera, and Vumerity in, among other jurisdictions, New York, North Carolina, Florida, Illinois, Kansas, Indiana, Virginia, Delaware, Pennsylvania, and New Jersey, other than for resale. Teamsters Local 237 bought these products directly from Biogen's co-conspiring specialty pharmacies (such as CVS Specialty Pharmacy and Aetna Specialty Pharmacy)

and indirectly from others. Teamsters Local 237 and other Class members paid more for Vumerity, Tecfidera, and its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, Teamsters Local 237 and the other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera or Vumerity, and would have paid less for generic Tecfidera.

36. During the Class Period, Teamsters Local 237 hired Aetna as their PBM to manage their pharmacy benefit, which included formulary management services. During the Class Period, that PBM restricted distribution of generic Tecfidera to specialty pharmacies, charging specialty pharmacy prices, and placed other formulary restrictions on generic Tecfidera, thereby disadvantaging generic Tecfidera.

37. Plaintiff New York State Teamsters Council Health and Hospital Fund ("NYST") is a self-insured health plan whose purpose is to provide health benefits to eligible members and dependents. NYST's principal place of business is located in Syracuse, New York. During the Class Period, NYST purchased, paid, and/or provided reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

38. During the Class Period, NYST purchased substantial amounts of Tecfidera, generic Tecfidera, and Vumerity on behalf of eligible members and dependents in, among other jurisdictions, New York, other than for resale. NYST bought these products directly from Biogen's co-conspiring specialty pharmacies (such as Accredo) and indirectly from others. NYST and other Class members paid more for Vumerity, Tecfidera, and its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, NYST and the

other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera or Vumerity, and would have paid less for generic Tecfidera.

39. During the Class Period, NYST hired Express Scripts as its PBM to manage its pharmacy benefit, which included formulary management services. During the Class Period, that PBM's formulary treated generic Tecfidera the same as brand Tecfidera and Vumerity so that insureds were charged the same copay for generic Tecfidera, Tecfidera and Vumerity, and placed other formulary restrictions on generic Tecfidera. Among other things, that PBM restricted distribution of generic Tecfidera to specialty pharmacies, charging generic specialty pharmacy prices.

40. Plaintiff UFCW Local 1500 Welfare Fund ("Local 1500") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with over 15,000 members, is the largest grocery union in New York. Local 1500 is a self-insured health and welfare benefit plan, and it purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

41. During the Class Period, Local 1500 purchased substantial amounts of Tecfidera and generic Tecfidera in, among other jurisdictions, New York, for the personal use of its members and beneficiaries, other than for resale. Local 1500 bought these products directly from Biogen's co-conspiring specialty pharmacies (such as Accredo). Local 1500 and other Class members paid more for Tecfidera or its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, Local 1500 and the other Class members would

have purchased more of the less expensive generic alternatives rather than branded Tecfidera, and would have paid less for generic Tecfidera.

42. During the Class Period, Local 1500 hired Express Scripts as its PBM to manage its pharmacy benefit, which included formulary management services. During the Class Period, that PBM's formulary restricted distribution of generic Tecfidera to specialty pharmacies, charging generic specialty pharmacy prices, and placed other formulary restrictions on generic Tecfidera, thereby disadvantaging generic Tecfidera.

43. Plaintiff Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("JPOFFHIT") is a health insurance trust that provides medical coverage, including pharmacy benefits, to its members. JPOFFHIT is organized under the laws of the State of Florida, with its principal place of business at 625 Stockton Street, Jacksonville, Florida 32204. JPOFFHIT purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

44. During the Class Period, JPOFFHIT purchased substantial amounts of Tecfidera, generic Tecfidera, and Vumerity in, among other jurisdictions, Florida, other than for resale. JPOFFHIT and other Class members bought these products directly from Biogen's co-conspiring specialty pharmacies (such as Accredo). JPOFFHIT and other Class members paid more for Vumerity, Tecfidera, or its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, JPOFFHIT and the other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera or Vumerity, and would have paid less for generic Tecfidera.

45. During the Class Period, JPOFFHIT hired Express Scripts as its PBM to manage its pharmacy benefit, which included formulary management services. During the Class Period, that PBM's formulary treated generic Tecfidera the same as Tecfidera so that the insured paid the same coinsurance for generic Tecfidera as brand Tecfidera, and placed other formulary restrictions on generic Tecfidera. Among other things, that PBM restricted distribution of generic Tecfidera to specialty pharmacies, charging generic specialty pharmacy prices.

B. Defendant

46. Defendant Biogen is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 225 Binney Street, Cambridge, Massachusetts. Biogen is a manufacturer and seller of branded prescription pharmaceuticals, including Tecfidera and Vumerity. It regularly conducts business throughout the United States, including in this judicial district.

47. All of Biogen's actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Biogen's various officers, agents, employees, or other representatives while actively engaged in the management of its affairs (or that of its predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Biogen.

C. Co-Conspirators

1. Co-Conspirator CVS Caremark

48. Co-Conspirator CVS Health Corporation ("CVS Health") is a corporation organized under the laws of the state of Delaware with its principal place of business located at 1 CVS Drive, Woonsocket, Rhode Island 02895. As described herein, CVS Health owns and

controls, among other entities, a major health insurer, the largest PBM operation in the U.S., a specialty pharmacy, a mail-order pharmacy, more than 9,000 brick-and-mortar retail pharmacies, and a rebate aggregator/group purchasing organization.

49. As further described herein, CVS Health and its various subsidiaries, including its PBM and specialty pharmacy units, operate as a single economic enterprise with financial, managerial, and operational control indistinguishable between the subsidiaries. Indeed, CVS Health files consolidated financial statements on behalf of itself and its subsidiaries, including its PBM and specialty pharmacy units, and states therein that references to "we' "our" or "us" in such reports should be interpreted to include all such subsidiaries, which includes its PBM and specialty pharmacy units. The public filings, documents, and statements of CVS Health present its subsidiaries as divisions or departments of a single, unified unit.

50. Co-Conspirator CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business at the same location as Co-Conspirator CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health. CVS Pharmacy is the immediate and direct parent of Co-Conspirator Caremark Rx, LLC.

51. Co-Conspirator Caremark Rx, L.L.C. is a Delaware limited liability company and its principal place of business is at the same location as CVS Pharmacy and CVS Health. Caremark Rx, L.L.C. is a PBM and a wholly owned subsidiary of Co-Conspirator CVS Pharmacy. Co-Conspirator Caremark, L.L.C. is a California limited liability company with its principal place of business at the same location as CVS Health. Caremark, L.L.C. provides PBM services and is a wholly owned subsidiary of Caremark Rx, L.L.C. Co-Conspirator CaremarkPCS Health, L.L.C. is a Delaware limited liability company with its principal place of business at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health L.L.C.

CaremarkPCS Health, L.L.C. provides pharmacy benefit management services. Caremark Rx, L.L.C., Caremark, L.L.C and CaremarkPCS Health, L.L.C. are collectively referred to as "Caremark."

52. Co-Conspirator Aetna, Inc. is also a subsidiary of CVS Pharmacy. Aetna, Inc. owns Aetna Health Holdings, LLC which owns Aetna Specialty Pharmacy LLC, a specialty pharmacy services provider. Aetna, Inc., Aetna Holdings, LLC and Aetna Specialty Pharmacy LLC are collectively referred to as "Aetna."

53. Co-Conspirator CVS Specialty Pharmacy[1] comprises limited liability companies that are indirect subsidiaries of Co-Conspirator CVS Pharmacy, most with principal places of business at the same location as CVS Health and Caremark. CVS Specialty Pharmacy provides specialty pharmacy services.

54. CVS Health has four reportable segments, one of which is Pharmacy Services. The Pharmacy Services unit includes both PBM services and specialty pharmacy services, which are provided by Caremark, Aetna and/or CVS Specialty Pharmacy as a single consolidated service.

55. In fact, CVS Health refers to the "Company's PBM" (meaning Caremark) as a CVS entity that fills prescriptions, and it identifies specialty and mail order pharmacy services as one of its "PBM Solutions" or "PBM Services" through its CVS Caremark operations, further indicating the CVS PBM and specialty pharmacy services are treated as one and the same, controlled by the Caremark PBMs and, ultimately, CVS Pharmacy and CVS Health. CVS Health admits it "controls

[1] CVS Specialty Pharmacy collectively and individually refers to Specialty Pharmacy, L.L.C. (Arizona); Caremark California Specialty Pharmacy, L.L.C. (California); Caremark Florida Specialty Pharmacy, LLC (Florida); Caremark Illinois Specialty Pharmacy, LLC (Illinois); Caremark Kansas Specialty Pharmacy, LLC (Kansas); Caremark Michigan Specialty Pharmacy, LLC (Michigan); Caremark Massachusetts Specialty Pharmacy, L.L.C. (Massachusetts); Caremark New Jersey Specialty Pharmacy, LLC (New Jersey); Caremark North Carolina Specialty Pharmacy, LLC (North Carolina); Caremark Tennessee Specialty Pharmacy, LLC (Tennessee); Caremark Maryland Specialty Pharmacy, LLC (Maryland); and Caremark Minnesota Specialty Pharmacy, LLC (Minnesota).

prescriptions fulfilled indirectly through its retail pharmacy network because it has separate contractual arrangements with those pharmacies, has discretion in setting the price for the transaction and assumes primary responsibility for fulfilling the promise to provide prescription drugs to its client plan members while also performing the related PBM services."

56. The integrated nature of specialty and PBM operations at CVS is well known in the industry. For example,co-conspirator Cigna/Express Scripts describes its competition as including "many PBMs [who] own and operate home delivery and specialty pharmacies" and lists CVS, Optum RX, and Humana as examples.

57. The integrated and consolidated operations of the various CVS entities, including in the provision of PBM and specialty pharmacy services, are further reflected in multiple interlocking directorships and shared executives. For example:

- Thomas S. Moffatt was Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, L.L.C., and Caremark, L.L.C. at the same time he was Vice President, Assistant Secretary, and Assistant General Counsel at CVS Health and Director, Vice President, and Secretary at CVS Pharmacy;
- Derica W. Rice was Executive Vice President of CVS Health at the same time he was President of CVS Caremark;
- Jonathan C. Roberts was Executive Vice President and Chief Operating Officer at CVS Health at the same time he was CEO of Caremark Rx, L.L.C; and
- Alan M. Lotvan, M.D., served as Executive Vice President of CVS Health Corporation and President of Caremark simultaneously.

58. In addition, the aforementioned Alan Lotvan, as well as Prem Shah, served as Vice Presidents of "Specialty Pharmacy-CVS Caremark," further reflecting the integrated nature of the

services and the Caremark PBM's input and control over the Specialty Pharmacy aspects of the integrated services.

59. The overlapping management and ownership structure, in conjunction with the unified financials and lack of operational autonomy, make the foregoing CVS entities—hereafter referred to collectively as "CVS-Caremark"—a single economic unit or enterprise for purposes of assessing their participation and involvement in the conspiracy.

60. CVS-Caremark has recently publicly admitted its status as a single economic unit or enterprise and the extensive vertical integration between its PBM and its closely affiliated mail order and specialty pharmacies. For example, CVS-Caremark publicly confirmed that:

a. one of the key services offered by its PBM is that *the PBM operates* specialty pharmacies that it owns or with which it is affiliated;

b. one way in which its PBM earns revenues and incurs costs is through the margins earned by its affiliated specialty pharmacies;

c. in the PBM's financial accounting, its revenues are defined as the sum of, among other things, certain payments made to affiliated specialty pharmacies, while its costs include those incurred on behalf of its affiliated specialty pharmacies;

d. the PBM controls the margins earned by its affiliated specialty pharmacies because those margins depend on the reimbursements they receive from the affiliated PBM;

e. the PBM's reimbursement rates to its affiliated specialty pharmacies are not set through arm's-length market transactions between independent parties, but instead occur within a vertically integrated company or single economic unit.

61. These self-disclosed facts about CVS-Caremark are consistent with recent analysis by Federal Trade Commission staff economists that each of CVS-Caremark, Express Scripts, and OptumRx "can shift revenue and profits between [its] 'upstream' PBMs and 'downstream' pharmacies. For example, when reimbursement rates are set high, PBMs generate less spread but their affiliated pharmacies generate more margin (and vice versa when reimbursement rates are set low)."

62. Similarly, an advocacy group dedicated to promoting the interests of its PBM membership (including CVS-Caremark, Express Scripts, OptumRx, Humana, and MedImpact) has indicated, both before Congress and in public sessions hosted by the federal antitrust agencies, that these PBMs directly operate their specialty pharmacies and have increasingly brought specialty pharmacy services in-house, with the prescriptions filled by PBM-affiliated mail-order and specialty pharmacies providing added margins to their PBMs.

63. Each of the CVS Caremark-affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged herein.

2. Co-Conspirator Express Scripts

64. Co-Conspirator The Cigna Group ("Cigna") is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located in Bloomfield, Connecticut. As described herein, Cigna owns and controls, among other entities, a major health insurer, one of the top three PBMs, a specialty pharmacy, a mail-order pharmacy, and a rebate aggregator.

65. As further described herein, Cigna and its various subsidiaries, including its PBM and specialty pharmacy units, operate as a single economic enterprise with financial, managerial, and operational control indistinguishable between the subsidiaries. Indeed, Cigna files consolidated financial statements on behalf of itself and its subsidiaries, including its PBM and specialty pharmacy units, wherein Cigna presents its subsidiaries as divisions or departments of one unified unit. For example, Cigna states that references to "Cigna," the "Company," "we," "our" or "us" refer to Cigna and its subsidiaries, which Cigna collectively describes as a "global health service organization" that provides various services "offered by our subsidiaries."

66. Co-Conspirator Evernorth Health, Inc. ("Evernorth"), formerly known as Express Scripts Holding Company, is a corporation organized under the laws of the state of Delaware with its principal place of business located at 1 Express Way, Saint Louis, Missouri, 63121. In 2018 Express Scripts Holding Company merged with Cigna in a $67 billion deal to consolidate their businesses. Today, Evernorth is a subsidiary of Cigna and owns and controls, among other entities, one of the top three largest PBMs, a specialty pharmacy, a mail-order pharmacy, a group purchasing organization, and a private drug labeler. Evernorth, through its executives and employees, is directly involved in shaping the company policies that inform its PBM and specialty pharmacy services.

67. Co-Conspirator Express Scripts, Inc. is a Delaware corporation and is a wholly owned subsidiary of Co-Conspirator Evernorth. Express Scripts, Inc.'s principal place of business is at the same location as Evernorth. Express Scripts, Inc., is directly involved in PBM and pharmacy services. Co-Conspirator Express Scripts Administrators, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC provides PBM services, and its principal place of business is at the same location as Evernorth. Express Scripts, Inc. and Express Scripts Administrators, LLC are collectively referred to as the "ESI PBMs."

68. Co-Conspirator Accredo Health Group, Inc. d/b/a Accredo Specialty Pharmacy ("Accredo") is a Delaware corporation and is a wholly owned subsidiary of Co-Conspirator Evernorth. Accredo Health's principal place of business is located at 1620 Century Center Parkway, Memphis, Tennessee. Accredo is a specialty pharmacy.

69. Co-Conspirator Express Scripts Pharmacy, Inc., is a Delaware corporation and is a wholly owned subsidiary of Co-Conspirator Evernorth. Express Scripts Pharmacy, Inc.'s principal

place of business is at the same location as Evernorth. Express Scripts Pharmacy, Inc. provides mail-order pharmacy services.

70. Cigna is organized in distinct reportable segments, one of which is the Health Services Segment. The Health Services Segment includes both PBM services and specialty pharmacy services, which are provided by the ESI PBMs and Accredo as a single consolidated service.

71. Cigna's public filings identify other PBMs, namely Caremark and Optum, as the entities against whom "Express Scripts *and Accredo*" (emphasis added) compete, indicating the ESI PBMs' and Accredo's specialty pharmacy services are treated as one and the same, controlled by the ESI PBMs and, ultimately, Evernorth and Cigna. Cigna's officers have made similar statements in testimony before Congress, identifying "specialty pharmacy care and distribution" as a service of Express Scripts and discussing the Therapeutic Resource Centers within Accredo, "our in-house specialty pharmacy," as being one of Express Scripts's many "tools" ranging from "an innovative specialty pharmacy care model" to more traditional PBM services such as "formulary management." The same testimony indicates Express Scripts "earn[s] tangible pharmacy revenues" from several sources, including "dispensing prescription drugs from our home delivery and specialty pharmacies."

72. The integrated and consolidated operations of the various Cigna entities, including in the provision of PBM and specialty pharmacy services, is further reflected by the sharing and movement of executives between companies. At least two executives simultaneously served at multiple Cigna companies, and other executives moved between positions at the ESI PBMs and Cigna. Specifically, Eric Palmer simultaneously held the roles of Executive Vice President at Cigna and Chief Executive Officer at Evernorth, and Timothy Wentworth simultaneously served

as President of Express Scripts and Cigna services. In addition, Steven Miller and Everett Neville were promoted from executive positions at an ESI PBM to Cigna.

73. The overlapping management and ownership structure, in conjunction with the unified financials and lack of operational autonomy, make the foregoing Cigna entities—hereafter referred to collectively as "Express Scripts"—a single economic unit or enterprise for purposes of assessing their participation and involvement in the conspiracy.

74. Express Scripts has recently publicly admitted its status as a single economic unit or enterprise and the extensive vertical integration between its PBM and its closely affiliated mail order and specialty pharmacies. For example, Express Scripts publicly confirmed that:

a. one of the key services offered by its PBM is that *the PBM operates* specialty pharmacies that it owns or with which it is affiliated;

b. one way in which its PBM earns revenues and incurs costs is through the margins earned by its affiliated specialty pharmacies;

c. in the PBM's financial accounting, its revenues are defined as the sum of, among other things, certain payments made to affiliated specialty pharmacies, while its costs include those incurred on behalf of its affiliated specialty pharmacies;

d. the PBM controls the margins earned by its affiliated specialty pharmacies because those margins depend on the reimbursements they receive from the affiliated PBM;

e. the PBM's reimbursement rates to its affiliated specialty pharmacies are not set through arm's-length market transactions between independent parties, but instead occur within a vertically integrated company or single economic unit.

75. Each of the foregoing Express Scripts affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged herein.

3. Co-Conspirator OptumRx

76. Co-Conspirator UnitedHealth Group, Inc. ("UHG") is a corporation organized under the laws of the state of Delaware with its principal place of business at 9700 Health Care Lane, Minnetonka, Minnesota 55343. UHG owns and controls, among other entities, a major

health insurer, one of the top three largest PBMs, a specialty pharmacy, a mail-order pharmacy, a private drug labeler, and a rebate aggregator/group purchasing organization.

77. As further described herein, UHG and its various subsidiaries, including its PBM and specialty pharmacy units, operate as a single economic enterprise with financial, managerial, and operational control indistinguishable between the subsidiaries. Indeed, UHG files consolidated financial statements on behalf of itself and its subsidiaries, including its PBM and specialty pharmacy units, wherein UHG presents its subsidiaries as divisions or departments of one unified unit. For example, UHG states that references to "we," "our," "us," "its," "UnitedHealth Group," or the "Company" used in its financial reports refer to UnitedHealth Group Incorporated and its subsidiaries.

78. Co-Conspirator Optum, Inc. is a Delaware corporation with its principal place of business in Eden Prairie, Minnesota. Co-Conspirator Optum, Inc., promotes itself as being accredited by the Utilization Review Accreditation Commission ("URAC") on its website. Co-Conspirator Optum, Inc., describes itself as a URAC-accredited specialty pharmacy and mail service pharmacy with multiple accredited specialty and mail order pharmacy sites that comprise Co-Conspirator Optum Specialty Pharmacy and Co-Conspirator Mail Service Pharmacy. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Co-Conspirator Optum Specialty Pharmacy, Co-Conspirator Mail Service Pharmacy, and Co-Conspirator OptumRx., Inc.

79. Co-Conspirator OptumRx, Inc. is a California corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, Minnesota. OptumRx, Inc. is, in part, a PBM and operates as a subsidiary of Co-Conspirator OptumRx Holdings, LLC. Co-Conspirator OptumRx Holdings, LLC is a subsidiary of Co-Conspirator Optum, Inc., and has its principal place

of business at the same location as Co- Conspirator OptumRx, Inc. Optum Rx, Inc. and OptumRx Holdings, LLC are together hereafter referred to as "Optum Rx."

80. UHG is organized in distinct reportable segments, one of which includes the services provided by Optum Rx. Optum Rx operates, owns and controls both PBM and specialty pharmacy services as part of its membership in the integrated UHG family of companies. Optum Rx identifies itself as a Pharmacy Benefit Manager whose services include "Delivery of Specialty Pharmacy products." Optum's PBM services include Optum Rx's vast specialty pharmacy operations, which it promotes as one of "Optum Rx's businesses" comprising "nearly 70 *specialty* and infusion *pharmacies* located throughout the United States…." (emphasis added). In testimony before Congress, an Optum Rx officer touted "our ownership of pharmacies" as enabling a "pharmacy care services model that is integrated with pharmacies that we [the PBM] operate." The Optum Rx officer described "[o]ur specialty pharmacies" as being "connected and integrated with access to a more complete range of PBM data." In press releases, UHG identifies the specialty pharmacy capabilities of new affiliates as being absorbed into Optum Rx's larger suite of services. As these statements establish, UHG's PBM and specialty pharmacy services are one and the same, provided through Optum Rx. Consistent with the integrated nature of the PBM and specialty pharmacy operations, UHG's consolidated financial reporting does not distinguish between the two and instead reports revenue and other metrics for both as simply "Optum Rx."

81. UHG acknowledges the deep integration of PBM and specialty pharmacy services stating: "The Company is also involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors' members and accordingly, product revenues are reported on a gross basis."

82. The integrated nature of specialty and PBM operations at UGH/Optum is well known in the industry. For example, Co-Conspirator Cigna/Express Scripts describes its competition as including "many PBMs [who] own and operate home delivery and specialty pharmacies" and lists CVS, Optum RX, and Humana as examples.

83. The integrated and consolidated operations of the various UHG entities, including in the provision of PBM and specialty pharmacy services, is further reflected by movement of executives and board members between companies. For example, board member Dick McMahon was Chief Executive Officer at Optum Rx before taking a position as Chief Operating Officer at UHG, and board member John Rex was Chief Financial Officer at Optum before taking the same role at UHG.

84. The overlapping management and ownership structure, in conjunction with the unified financials and lack of operational autonomy, make the foregoing UHG entities—hereafter referred to collectively as "Optum"—a single economic unit or enterprise for purposes of assessing their participation and involvement in the conspiracy.

85. OptumRx has recently publicly admitted its status as a single economic unit or enterprise and the extensive vertical integration between its PBM and its closely affiliated mail order and specialty pharmacies. For example, OptumRx publicly confirmed that:

a. one of the key services offered by its PBM is that *the PBM operates* specialty pharmacies that it owns or with which it is affiliated;

b. one way in which its PBM earns revenues and incurs costs is through the margins earned by its affiliated specialty pharmacies;

c. in the PBM's financial accounting, its revenues are defined as the sum of, among other things, certain payments made to affiliated specialty pharmacies, while its costs include those incurred on behalf of its affiliated specialty pharmacies;

d. the PBM controls the margins earned by its affiliated specialty pharmacies because those margins depend on the reimbursements they receive from the affiliated PBM;

e. the PBM's reimbursement rates to its affiliated specialty pharmacies are not set through arm's-length market transactions between independent parties, but instead occur within a vertically integrated company or single economic unit.

86. Each of the foregoing OptumRx affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged herein.

4. Co-Conspirator Humana Inc.

87. Co-Conspirator Humana Inc. ("Humana") is a Delaware corporation, with its principal place of business located at 500 West Main Street, Louisville, Kentucky 40202. Humana owns and controls: (a) Humana Pharmacy Solutions, Inc. ("HPS"), the PBM; (b) CenterWell Specialty Pharmacy (f/k/a Humana Specialty Pharmacy), a specialty pharmacy service provider; and; (c) CenterWell Pharmacy (f/k/a Humana Pharmacy), a mail-order pharmacy.

88. As further described herein, Humana, its PBM, and its pharmacy subsidiaries operate as a single economic unit with unified financial, managerial, and operational control indistinguishable between the subsidiaries. Indeed, Humana files consolidated financial statements on behalf of itself and its subsidiaries, including Humana Pharmacy Solutions, CenterWell Specialty Pharmacy, and CenterWell Pharmacy, and states therein that references to "we," "our," "us," "Company," or "Humana" in such reports should be interpreted to include all subsidiaries, which includes those identified herein. The public filings, documents, and statements of Humana present its subsidiaries as divisions or business units of a single, unified entity.

89. In its public filings, Humana describes its pharmacy solutions business as including "the operations of CenterWell Pharmacy (our mail-order pharmacy business), CenterWell Specialty Pharmacy, and other retail pharmacies located within" its primary care clinics.

90. Humana reports that the profitability of its reportable segments, which include the PBM business and pharmacy solutions, is interdependent, given that Humana allocates indirect costs shared by the segments as a function of revenues.

91. During the Class Period, Humana has had either three or two reportable segments. Before December 2022, Humana's public filings identified three reportable segments: Retail, Group and Specialty, and Healthcare Services. The Healthcare Services segment included pharmacy solutions and the PBM business. Since December 2022, Human's public filings have identified two reportable segments: (1) Insurance, which includes operations of the PBM business; and (2) Centerwell, which includes pharmacy solutions. Humana has reported in its public filings that its most recent structure of its reportable segments "will create greater collaboration across [the] businesses . . . and will accelerate work that is underway to centralize and integrate operations within the organization."

92. Humana's 2024 10-Q notes that "Humana" means "Humana Inc. and its subsidiaries," including Humana Pharmacy Solutions, CenterWell Pharmacy, and CenterWell Specialty Pharmacy.

93. The integrated nature of specialty and PBM operations at Humana is well known in the industry. For example, Co-Conspirator Cigna/Express Scripts describes its competition as including "many PBMs [who] own and operate home delivery and specialty pharmacies" and lists CVS, Optum RX and Humana as examples.

94. HPS has its principal place of business in the same location as Humana. Humana has reported that HPS, the PBM, "also operates prescription mail order services for brand, generic, and specialty drugs . . . through Humana Pharmacy, Inc."

95. CenterWell Specialty Pharmacy and CenterWell Pharmacy have their principal place of business in Cincinnati, Ohio.

96. The integrated and consolidated operations of the various Humana entities, including in the provision of PBM and specialty pharmacy services, is further reflected in multiple interlocking directorships and shared executives. Throughout the Class Period, Humana's public filings have identified Executive Officers of the "Company," which includes Humana and its subisidiaries, including the foregoing. Furthermore, Humana's Executive Officers include individuals who have responsibility for the reporting segments, which include the PBM business and pharmacy solutions. For example, Dr. William K. Fleming, PharmD concurrently served as the Segment President of Pharmacy Solutions (CenterWell) and Chief Corporate Affairs Officers. Prior to that he was Segment President of Healthcare Services, which included the PBM business and pharmacy solutions, and he was President of the Company's pharmacy business.

97. The overlapping management and ownership structure, in conjunction with the unified financials and lack of operational autonomy, make the foregoing Humana entities a single economic unit or enterprise for purposes of assessing their participation and involvement in the conspiracy.

98. Each of the foregoing Humana-affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged herein.

5. Co-Conspirator MedImpact Healthcare Systems, Inc.

99. Co-Conspirator MedImpact Healthcare Systems, Inc. ("MHS") is a corporation organized under the laws of the State of California, with its principal place of business at 10181 Scripps Gateway Court, San Diego, California 92131. As described herein, MHS owns and

controls: (1) Birdi, Inc., a mail-order pharmacy; and (2) Specialty By Birdi, a specialty pharmacy (together, "MedImpact").

100. MedImpact and its affiliates operate as one single economic unit with unified financial, managerial, and operational control. Public filings for MedImpact present the PBM, Birdi, Inc., and Specialty By Birdi as divisions or business units of one consolidated enterprise, sharing executives, systems, and financial statements across all three entities.

101. MHS (the PBM) provides pharmacy benefit management services like formulary design and management, rebate negotiation, claims processing, and network administration to health plans and employers.

102. MHS is the largest private PBM in the United States and covers more than 50 million lives.

103. Birdi, Inc., MedImpact's mail order pharmacy, is a Delaware corporation with with a principal place of business at the same location as MHS.

104. James L. Gollaher is both a Director of Birdi, Inc. and acts as the CFO of MHS.

105. Specialty By Birdi, MedImpact's specialty pharmacy, is a tradename owned by MedImpact.

106. Each of the foregoing MedImpact-affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged herein.

107. All of the Co-Conspirators CVS Caremark, Express Scripts, OptumRx, Humana, and MedImpact, are collectively referred to herein as "PBMs," and their wrongful actions described in this Complaint are part of, and in furtherance of, the unlawful restraints of trade alleged herein, and were authorized, ordered, and/or undertaken by the Co-Conspirators' various officers, agents, employees, or other representatives while actively engaged in the management of

the Co-Conspirators' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Co-Conspirators.

D. Plaintiffs' Purchases of the Products

108. One of the key services offered by the Co-Conspirator PBMs is operating specialty pharmacies that the PBMs own or control. See Section II(C) above.

109. Plaintiffs purchased Tecfidera, generic Tecfidera, and Vumerity from multiple sources. During the class period, Plaintiffs purchased a portion of their Tecfidera, generic Tecfidera, and Vumerity requirements directly from these co-conspiring specialty pharmacies. These speciality pharmacies were, as discussed herein, owned or controlled by Co-Conspirators within the same, single corporate enterprise, including co-conspiring PBMs.

110. Biogen sold some of its Tecfidera and Vumerity products directly to the co-conspiring specialty pharmacies that, in turn, re-sold the product to Plaintiffs.

111. Biogen's public statements acknowledge this aspect of its distribution chain, that is, Biogen's direct sales of product to specialty pharmacies: "We distribute our products in the U.S. principally through wholesale and specialty distributors of pharmaceutical products *and specialty pharmacies, mail order specialty distributors* or shipping service providers" (emphasis added).

112. Specialty pharmacies, such as the co-conspiring CVS specialty pharmaices, similarly acknowledge their procurement of pharmaceuticals directly from brand-drug manufacturers: "As one of the nation's largest and most experienced providers of *specialty pharmacy services*, *we negotiate with drug manufacturers* for the most competitive prices and access to complex, expensive therapies" (emphasis added).

113. With respect to the products that Biogen sold directly to a co-conspiring specialty pharmacy that, in turn, sold the product directly to Plaintiffs, Plaintiffs and the Classes are direct purchasers from the conspiracy, and they bring their antitrust claims for damages under federal law—Sections 1 and 2 of the Sherman Act, Section 2(c) of the Robinson-Patman Act, and Section 4(a) of the Clayton Act.

114. In addition to Plaintiffs' direct purchases from co-conspiring specialty pharmacies that purchased directly from Biogen, Plaintiffs also purchased a portion of their Tecfidera, generic Tecfidera, and Vumerity requirements from pharmacies that first procured the products through wholesalers.

115. For branded Tecfidera and Vumerity purchased through wholesalers, or from others that purchased through wholesalers, Plaintiffs and Class members were harmed because, among other reasons, they purchased far greater amounts of these vastly more expensive branded products than they would have absent Biogen's unlawful conduct.

116. With respect to the products that Plaintiffs and the Class members bought through a source other than a co-conspiring specialty pharmacy, they bring their antitrust and consumer protection claims for damages under state laws that permit such claims by indirect purchasers.

117. With respect to the products that Plaintiffs and the Class members bought through any source, they bring their antitrust claims for injunctive relief under both federal and state law.

118. Plaintiffs' and Class members' claims for violation of RICO's substantive prohibitions are based on the corruption of benefit plan services that the PBMs provide to ERISA plans, not to other entities in the supply chain such as wholesalers or retailers. Similarly, the RICO violations arise from bribes or other improper payments that Biogen made to the PBMs for the purpose of influencing ERISA plans' actions, decisions, or duties—not bribes to other supply chain

intermediaries and not for the purpose of influencing any other entities' actions or duties. So Plaintiffs and Class members assert damages claims under RICO with respect to all of their purchases of the products affected by the RICO violations, from whatever source Plaintiffs and Class members bought the products.

III. JURISDICTION AND VENUE

119. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of Biogen.

120. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Biogen's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, and under Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a), for damages and other relief to remedy Biogen's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. § 1 and 2 and of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c). Further, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c) because Plaintiffs bring RICO claims under 18 U.S.C. § 1962(c). The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

121. This Court has personal jurisdiction over Biogen under Section 12 of the Clayton Act, 15 U.S.C. § 22. Further, this Court has personal jurisdiction over Biogen under Section 18 U.S.C. § 1965(b) because RICO, like the Clayton Act, authorizes nationwide service of process. The Court also has personal jurisdiction over Biogen under the Illinois long-arm statute, 735 ILCS 5/2-209(a)(7). The claims of Plaintiffs and the Class members arise out of or relate to Biogen's

conduct in this district. Plaintiffs and certain Class members made relevant purchases here; Biogen employs salespeople based in this district to market Biogen's products, including convincing doctors here to prescribe Tecfidera and Vumerity; Biogen advertises Tecfidera and Vumerity to people living in this district, including running a national television advertising campaign for Tecfidera that targeted and reached residents of this district; and Biogen's unlawful conduct caused PBMs to disadvantage generic Tecfidera on formularies covering residents of this district and caused health plans and consumers in this district and elsewhere to incur overcharges on their purchases covered by those formularies.

122. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. §1391(b) and (c), because Biogen transacts business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue is also appropriate under 18 U.S.C. § 1965(a) because Biogen employs agents based in this district, transacts its affairs in this district, and is found in this district as described above.

IV. THE IMPORTANCE OF GENERIC DRUGS

A. The High Price of Branded Drugs

123. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit to get or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the product's price plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower their prices.

124. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Tecfidera and Vumerity, to patients without a prescription written by a doctor. The prohibition on dispensing the drug without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the drug, but the patient's doctor chooses which drug the patient (and his or her insurer) will buy.

125. Biogen and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are less sensitive to price differences because they do not have to pay for the drugs. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

126. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—a measure of the extent to which unit sales go down when price goes up. This reduced price elasticity among brand-drug alternatives in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power.

127. The result of the market imperfections and marketing practices described above is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure that Promotes Generic Drugs

128. The relevant drug-regulation framework is established by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments"). Under the FDCA, branded drug manufacturers that wish to sell a new drug product must obtain approval from the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(b). The NDA must include, among other things, a statement of the drug's components, active ingredients, scientific data showing that the drug is safe and effective, patent information, and proposed labeling describing the methods by which a drug may be used and administered. 21 U.S.C. §§ 355(a), (b).

129. Upon FDA approval of the NDA, the FDA requires the manufacturer to identify any patents that it asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the listed patents expire. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness.

130. The Hatch-Waxman Amendments speed generics onto the market. The Amendments' fundamental premise is that many branded prescription drugs have market power and that only competition from generic drugs can bring competitive prices. The evidence on which Congress relied showed that, even after brand-drug patents had expired, competition among branded drugs was insufficient to deliver competitive prices. Only competition from generic drugs could drive prices to the competitive level.

131. The Amendments speed generics onto the market several ways. The Amendments simplify the regulatory hurdles for generic manufacturers by eliminating the need for them to file

lengthy and costly NDAs. Instead, generic manufacturers can file an Abbreviated New Drug Application ("ANDA"), which relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. The generic manufacturer need only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterpart.

132. The FDCA and Hatch-Waxman Amendments operate on the basis that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent. Bioequivalence demonstrates that the proposed generic drug's active ingredient would be present in the patient's blood to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). So a generic drug that receives an AB rating from the FDA may safely be substituted for the brand drug.

133. In addition to easing FDA approval for generic drugs, the Hatch-Waxman Amendments also ease their pathway through litigation over the brand manufacturer's patents. A generic manufacturer that certifies that its product will not infringe the brand's patents may be able to litigate the patents' validity and applicability without subjecting itself to patent-infringement damages if it were to lose the litigation. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). And Congress encouraged manufacturers to challenge brand-drug patents, providing a valuable period of generic-drug exclusivity—essentially, a financial bounty often worth hundreds of millions of dollars—for

the first manufacturer that initiates a challenge to a brand patent. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

134. State legislation has supplemented Congress's efforts to speed generics onto the market. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

135. Like the Hatch-Waxman Amendments, these state drug-product substitution laws are founded on the premise that, before generic entry, branded drugs typically have market power. If they did not have market power, there would be little or no need for state laws that permit or require the pharmacist to substitute a generic.

136. The combined federal and state efforts to promote generic competition—when not undermined by manufacturers' or others' anticompetitive conduct—have been largely successful. In 1983, before the Hatch-Waxman Amendments and state generic-substitution laws, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. By 2013, generic drugs accounted for 86% of all prescriptions dispensed. Today, generics are dispensed 95% of the time when a generic version is available.

C. The Competitive Effects of AB-rated Generic Competition

137. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. The only material difference between generic drugs and their corresponding brand-name versions are their prices.

138. Generic versions of a corresponding branded drug product are commodities that are not differentiated, so the primary basis for generic competition is price. Typically, generics are at

least 25% less expensive than their brand-name counterparts when there is a single generic competitor, and this discount typically increases to 80% (or more) when multiple generic competitors are on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

139. Once a generic equivalent hits the market, the generic quickly takes sales from the corresponding branded drug, often capturing 90% or more of the market within the first six months, and 95% or more during the first 12 months. As a result, brand drug companies, including Biogen, view competition from generic drugs as a grave threat to their bottom lines.

140. By impairing generic competition, the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, including Biogen, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers therefore try to extend their monopoly for as long as possible by impairing generic competition, sometimes resorting to any means possible—including illegal means.

V. THE PROMISE AND PERILS OF PBMS

141. PBMs manage prescription drug benefits on behalf of their clients, which include health insurance companies, self-funded health plans, large companies, and governmental entities.

A. The Promise

142. One of the principal roles for PBMs is to create and maintain a drug formulary for the PBM's clients. A formulary is a list of prescription drugs for which the health plan will reimburse pharmacies on behalf of the plan's members. The formulary also describes the copayment or coinsurance for which the covered patient is responsible. A proper formulary will almost always provide a lower copayment or coinsurance for generic drugs as compared to their brand-drug counterparts. This incentivizes the patients to demand or accept the generic drug.

143. The purpose behind a proper drug formulary is to provide quality care using the most cost-effective options. If a drug is not included on a formulary, the health plan generally will not cover the cost of the drug. Thus, if a doctor prescribes a drug that is not on the formulary, the patient will be required to pay the entire cost of the drug out-of-pocket.

144. Prominent among PBMs' proper roles is to aggressively promote the use of generic drugs whenever possible. As noted above, generic drugs can quickly deliver discounts of 90% or more off the price of the branded drug.

145. A properly acting PBM has several powerful tools available to promote insureds' use of generic drugs when they are available. Important among these is placing the generic on the most advantageous tier on the formulary and on a more advantageous tier than the reference brand product.

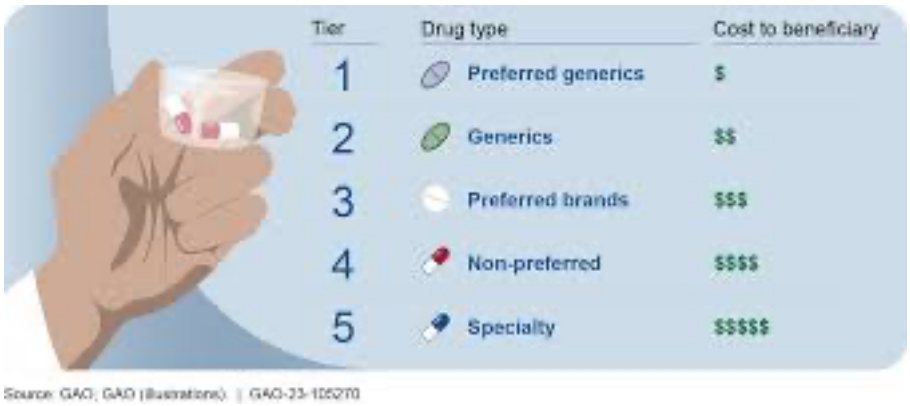
146. When rival drugs are available to treat the same condition, a PBM's formulary may prefer certain of those drugs over other "non-preferred" drugs. When PBMs are not bribed to do otherwise, their formularies use a "tier" system to promote effective but less costly drug alternatives.

147. PBMs place drugs into different tiers on their formularies, with three to five tiers being typical. Generally, drugs in a lower-numbered tier cost beneficiaries less than drugs in higher-numbered tiers, with generic drugs on the lowest-numbered tier and brand-name and specialty drugs on a higher-numbered tier. For example, tier 1 may include most generic prescription drugs, while tier 5 may include specialty drugs, which include high-cost prescription drugs with the highest cost-sharing.

148. Formularies typically provide for lower patient cost-sharing—the amount the insured must pay through copayments or coinsurance—for drugs on the lowest-numbered (i.e., the best) tier. Properly acting PBMs almost always promote generic drugs by placing them on Tier 1.

149. For both generic and brand-name drugs, PBMs may offer preferred and non-preferred tiers. Drugs in preferred tiers are generally more cost-effective than drugs in non-preferred tiers. Preferred brand-name and generic drugs also generally have lower cost-sharing than non-preferred brand-name and generic drugs.

150. Cost sharing can vary substantially by tier. For example, among those in plans with four tiers, average cost-sharing ranged from $12 copayment or 20% coinsurance for first tier/preferred drugs to a $124 copayment or 32% coinsurance for fourth tier drugs. Such tiering promotes the use of lower cost drugs that are more accessible, such as generics, on the lower tiers compared to the more costly nonpreferred brand drugs typically included on the higher tiers.



Source: GAO; GAO (illustrations). | GAO-23-105270

151. In addition to formulary tiers, PBMs can promote generic drug use by implementing drug utilization management tools. These tools promote generic drugs over brands by imposing restrictions on dispensing brand drugs, such as requiring prior authorization (which involves a review and sign-off by a PBM-employed health care provider before a patient can obtain a prescribed drug), step therapy (which requires a patient to try a preferred option on the formulary

before the insurer will cover the originally-prescribed drug), and quantity limits (such as restricting the number of doses a patient can receive for a particular condition).

152. Promoting generic drugs instead of brands is a principal way for PBMs to control drug costs for health plans and patients. In 2020 alone, the use of generic medicines saved the healthcare system an estimated $313 billion. On average, patients pay only $6.97 out of pocket for generic medicines, with over 90% of generic prescriptions costing patients less than $20 in 2020.

153. PBMs also create pharmacy networks through which the insureds get their covered prescriptions filled. This typically includes mail order pharmacies in addition to "brick and mortar" pharmacies.

154. In sum, through their control of formularies and pharmacy networks, PBMs have a prominent role in determining which drugs will be accessible to patients and at what cost.

1. PBMs promise to promote generic drugs and reduce health plans' costs.

155. PBMs are in a position of superior knowledge and special expertise regarding the administration of prescription drug benefits and market their superior knowledge and special skills as a means of lowering costs for their client health plans.

156. Health plans rely on PBMs to serve as their intermediaries and/or fiduciaries with drug manufacturers in connection with negotiating drug prices and formulary placement, and obtaining prescription drug cost savings. Lacking the resources or pharmaceutical expertise necessary to develop their own formularies, health plans generally rely entirely on PBMs for drug formulary decisions and accept what the PBMs offer. Indeed, PBMs invite their health plan clients to completely rely on the PBMs to negotiate prescription drug prices and develop formularies. Given that invited reliance and the PBMs' special expertise and skill, PBMs maintain a fiduciary relationship with respect to their health plan clients in connection with the management of their

respective pharmacy benefit plans, the development of formularies, and the negotiation of drug prices with manufacturers.

157. Each PBM Co-Conspirator has made representations touting its expertise and knowledge regarding the administration of prescription drug benefits, including the development of formularies to promote cost savings. Each PBM has acknowledged its role as an intermediary acting on behalf of its health plan clients.

158. Co-Conspirator Express Scripts has made the following representations, among others, regarding its responsibilities as an intermediary acting on behalf of its health plan clients:

a. In 2022, Express Scripts published its "Client Pledge" in its annual report, signed by its then Chairman and CEO Barrett Toan. In the Client Pledge, Express Scripts stated: "We pledge to: [1] Always align our interests with those of our clients and their members … [3] Aggressively promote the use of generic drugs; … [and 5] Never recommend switching a member to a higher-cost drug."

b. "PBMs save plan sponsors and consumers money … We negotiate with the big drug manufacturers and retail pharmacies across the United States to get the best possible prices for our clients. Our business model is one of alignment. We make money when plan sponsors and consumers save money."

c. "Our job is to bring down the cost, both for the patient and the plan sponsor, and do what is right. We are not tied to whether it is a brand or a generic. We want the lowest cost possible for our members to drive down the cost of health care."

d. "Express Scripts uses clinical expertise and scale to negotiate lower drug costs with drug manufacturers, leveraging competition to help drive savings for clients, which include employers, labor unions, health plans, the federal government, and states. These negotiations serve to create competition in the market for prescription drugs. The discounts negotiated in the supply chain for our clients ultimately benefit patients in the form of lower premiums and reduced out-of-pocket costs."

e. "Express Scripts relentlessly advocates on behalf of our clients and their members to make lifesaving therapies and medications more affordable."

f. "How Express Scripts creates value for you: We do this by negotiating deeper discounts—including rebates and formulary tiers—after drug manufacturers set list prices. The value is passed on directly to our clients, who decide how they want to use the cost savings. We partner across the supply chain and work to: [d]rive down drug spend [and] … [a]chieve lower drug list prices."

g. "Right now, biologics are extremely expensive with annual costs of $50,000 or more. In many cases, these annual costs can exceed hundreds of thousands of dollars for a single patient. Biosimilars, on the other hand, are estimated to be up to 35% less expensive than their branded reference biological products … Plan sponsors … need to ensure their plan is designed to prioritize the lowest cost, clinically-equivalent therapy, in addition to supporting members and providers throughout the transition process. Both of these objectives can be achieved by leveraging the full range of formulary and utilization management tools … [P]lan sponsors need to stay up-to-date on this ever-dynamic, increasingly complex space. Given all the fluid factors at play, from the intricacies of biologics and interchangeability (or not) to pricing preferences and approved indications, there's a lot to navigate. Evernorth is here to help. We have the experience and expertise to help keep plan sponsors informed and ahead of the curve with proactive guidance and proven solutions."

h. "In any industry, competition is the linchpin for driving down prices, and the U.S. pharmaceutical market is no exception. Left unchecked, drug manufacturers often escalate prices for their products to the maximum that the market can bear until competitors emerge. Whether the competition involves branded medications intended for the same condition or pits brands against their generic or biosimilar equivalents, pharmacy benefit managers (PBMs) like Express Scripts leverage the availability of alternative products to negotiate price discounts … By continuing to foster competition with effective biosimilars, Express Scripts can further bend pharmaceutical trends for plan sponsors, supporting savings today and drug innovation in the future."

159. Co-Conspirator CVS Caremark has made the following representations, among others, regarding its responsibilities as an intermediary acting on behalf of its health plan clients:

a. "CVS Caremark is more than a manager of pharmacy benefits–we are collaborators with our customers … Through our scale, expertise, and negotiating power, we can help you drive to low trend and spend across both traditional and specialty drugs. It's our job to go head-to-head with pharmaceutical manufacturers to negotiate the lowest possible prices on behalf of our clients. By removing as many drug pricing challenges as possible, we can help increase access and adherence, close gaps in care, and lower overall health care spend."

b. "We work with clients to design plan options that work for them. As for providers and members, we help them make more informed decision to help keep pharmacy costs down."

c. CVS Caremark "assists its PBM clients in designing pharmacy benefit plans that help improve health outcomes while minimizing the costs to the client … The Company makes recommendations to help PBM clients design benefit plans that promote the use of lower cost, clinically appropriate drugs and helps its PBM

clients control costs by recommending plan designs that encourage the use of generic equivalents of brand name drugs when such equivalents are available."

d. CVS Caremark's "formularies provide recommended products in numerous drug classes to help ensure member access to clinically appropriate drugs with alternatives within a class under the client's pharmacy benefit plan, while helping to drive the lowest net cost for clients that select one of [CVS Caremark's] formularies."

e. "At CVS Health, we have undertaken comprehensive efforts to help reduce the cost of drugs. Our pharmacy benefit management (PBM) business, CVS Caremark, employs three primary PBM techniques: [i] Encourage the use of lower-cost alternatives, such as generic medications through step therapy; [ii] Use prior authorization to help ensure patients utilize appropriate medications according to evidence-based rules; [and iii] Obtain lower costs for drugs by using competition to determine formulary placement when more than one clinically equivalent drug is available."

f. "If, as some assert, PBMs are only interested in higher prices, why do they push lower-cost generics? The answer–and simple truth–is that the PBM business model is built on getting the lowest cost for medications, encouraging the use of the lowest-cost alternatives, and helping members achieve optimal adherence to medications."

g. "CVS Caremark develops formulary plan design strategies to obtain rebates and discounts from pharmaceutical manufacturers on behalf of payors, to help control costs. Most drug classes have multiple competing drugs, which clinical experts consider 'clinically equivalent.' When that is the case, the PBM adds the drug with the lowest net cost–that is, the manufacturer-set price minus the rebate or discount–and removes higher-cost clinically equivalent drugs within the same therapeutic class from the formulary."

h. "Our goal as a pharmacy benefit manager (PBM) is simple: to reduce costs and improve health outcomes. We do this by negotiating discounts with manufacturers, designing formularies that encourage the use of generics and biosimilars, and creating new tools to help bring escalating drug prices under control. Our work on behalf of our clients to deliver the lowest cost medicines and the best possible outcomes helps them maintain a healthy workforce at an affordable price."

i. "What we do is create value for the employers, health plans and government programs we serve in four key ways: First, we negotiate the lowest cost possible on behalf of our clients and foster competition among drug manufacturers when more than one clinically-equivalent drug is available. Second, we encourage the use of generics and lower-cost biosimilars because they are proven to improve adherence and outcomes, while also lowering costs…"

j. "We negotiate the best possible discounts off the manufacturer's price on behalf of employers, unions, government programs, and the beneficiaries that we serve."

k. "In our work as a pharmacy benefit manager (PBM), CVS Health works to negotiate lower costs of prescription drugs, going head-to-head with drug manufacturers to remove as many drug pricing challenges as possible for our customers and their members … We negotiate discounts for our customers that help lower the cost of prescription drug coverage."

l. "PBMs enhance competition in the marketplace. Drug manufacturers set the prices of prescription drugs. We strive to promote competition among drug manufacturers to help drive down drug costs. PBMs enhance competition through group purchasing and negotiated discounts. We leverage the collective buying power of our members and the availability of competing brand drugs within therapeutic classes to achieve low net costs for clients and their members. Discounts we negotiate by driving competition are why customers choose to use PBMs, which are one of the few parts of the supply chain dedicated to lowering drug costs."

m. "Customers choose us for our ability to seamlessly administer complex pharmacy benefits to their members … Our role is help keep prescription drugs affordable."

n. "Pharmacy benefit managers, or PBMs, manage prescription drug benefits for clients ranging from health insurers and Medicare Part D drug plans to large employers. PBMs are one of the few parts of the prescription drug chain specifically dedicated to lowering costs."

o. "We help people navigate their health care by improving access, lowering costs, and being a trusted partner for every meaningful moment of their health. Our pharmacy benefit manager (PBM) supports this mission by bringing value to consumers and our clients, which include employers, unions and government health plans, by working to lower prescription drug costs."

p. "CVS Caremark uses formulary management and preferred placement to negotiate better pricing and greater discounts that reduce costs for payors when clinically equivalent alternatives are available."

q. "[O]ur biosimilars approach is consistent with our broader formulary strategy: helping drive lower net costs for payors without sacrificing coverage of clinically effective medications or continuity of care."

r. "CVS Health is deeply committed to driving the adoption of low-cost, high-quality medicines … CVS Health has embraced innovative approaches to promoting the adoption of generic and biosimilar drugs."

s. "At CVS Health, we are committed to using every tool possible and continuing to drive innovation to bring down the cost of drugs. We remain focused on providing the right drug to the right patient at the right time at the lowest possible cost."

t. "Delivering low net cost remains the foundation of our formulary approach."

u. "Using a combination of comprehensive surveillance and strategic drug removals, we promote clinically appropriate coverage, preserve member experience and help prevent wasteful spend … We remove hyperinflated drugs from our formularies that have readily available, clinically appropriate and more cost-effective alternatives, delivering timely savings for clients."

v. "Each year we evolve our formulary strategies to keep clients ahead of a rapidly changing market. Such an innovative approach to formulary management has helped save our clients tens of billions of dollars. Negotiating discounts from manufacturers, as well as developing and implementing proactive solutions—such as utilizing generic and biosimilar drugs to drive competition within a therapy class—are some of the many ways we continue to focus on helping our clients save money."

160. Co-Conspirator OptumRx has made the following representations, among others, regarding its responsibilities as an intermediary acting on behalf of its health plan clients:

a. "OptumRx negotiates better prices with drug manufacturers for our customers and consumers. OptumRx delivers value for our customers and the consumers we serve through a number of services, including negotiating lower drug costs … It is important to recognize that pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working to reduce costs for their customers and the only ones able to effectively negotiate with drug companies. OptumRx manages pharmacy benefits on behalf of customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and federal and state government employee plans. In that role, we promote use of clinically effective, lowest net-cost prescription drugs for consumers when medications are needed."

b. "If there is more than one drug in a particular class, Optum Rx gives preferable placement on its formulary to the drug with the lowest overall cost to our customer. For about 90 percent of prescriptions processed, OptumRx can identify a low-cost generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or 'on-patent') drug."

c. "PBMs, like Optum Rx, are the key counterweight to pharmaceutical companies' otherwise unchecked monopoly power to set and raise drug prices."

d. "PBMs are really the only effective mechanism across the system, which really holds the pharmaceutical company to account once it chooses to set its price, and by the way, also has the freedom to inflate its price every single year, which we see happen. The PBM is there to try and hold that to account and negotiate on behalf of employers, unions, states and others to try and bring down those prices … The PBM acts on behalf of the ultimate payer, the employer, the union, the state and such. It acts on their behalf, because they're ultimately the ones who are typically

underwriting the ultimate cost of the medicine for the patients, the consumers who are beneficiaries of their plans that are supported by those organizations."

e. In describing its PBM business its website, Optum discusses "generic drugs" as a "particular example of how PBMs are closely aligned with their clients' needs." Optum states: "Both PBMs and their clients are aligned on the need to implement benefit designs that promote generics. The reason is simple: the programs same money and help promote better health outcomes."

161. Co-Conspirator Humana has made the following representations, among others, regarding its responsibilities as an intermediary acting on behalf of its health plan clients:

a. "Humana encourages the use of generic and cost-effective brand medications whenever possible."

b. Humana's pharmacy solutions "may lead to lower utilization associated with improved member health and/or lower drug costs."

c. "Our business strategy involves providing members and providers with easy to use products that leverage our information to meet their needs."

d. "Our successful history in care delivery and health plan administration is helping us create a new kind of integrated care with the power to improve health and well-being and lower costs."

e. Humana offers plans and solutions that provide "cost predictability."

f. Humana identifies opportunities to reduce its clients' prescription drug costs.

162. Co-Conspirator MedImpact has made the following representations, among others, regarding its responsibilities as an intermediary acting on behalf of its health plan clients:

a. "Our formularies are designed to achieve the lowest net cost by employing strategies that align with client goals."

b. "We help employers navigate the complexities of the healthcare system and manage costs…"

c. "MedImpact is pharmacy neutral, unaffiliated with care providers, not owned by a health plan, and always on the side of our clients."

d. "MedImpact rejects industry practices that allow PBMs to earn more when their clients and members pay more."

e. "MedImpact's unique model allows us to leverage multiple fulfillment partners to identify the lowest cost and best service for each class of medication."

f. "We proactively monitor the drug pipeline to help payers leverage new opportunities—improving member health while managing costs."

g. "For more than 35 years, MedImpact has been lowering drug spend, improving care, and delivering better solutions for our clients."

h. "MedImpact is the PBM that puts clients and consumers first. For 30 years, it has had one single mission: To make pharmacy benefits affordable and understandable."

i. "Our focus on transparency, low-net cost, and oversight allows us to put clients and consumers first. In an era focused on drug costs and pricing transparency, MedImpact understands the importance of drug cost management … We are dedicated to promoting the interests of our plan and pharmacy partners, not competing against them. That is why we don't own mail-order or specialty pharmacies that can put a PBM's interest in conflict with those of its clients."

j. "Our forward-thinking approach and unique business model aligns us with your goals—it's what differentiates us from other PBMs."

k. "Our client- and member-first approach to pharmacy benefits and focus on clinical quality and rigorous utilization management—rather than chasing rebate dollars—allows us to align with our clients and members to deliver lower-cost, quality care."

2. Health plans rely on the PBMs' promises and their expertise.

163. Plaintiffs and other Class members are in no position to detect or prevent brand manufacturers' and PBMs' anticompetitive conduct with respect to specific drugs. Health plans hire and trust the PBMs to create and manage drug formularies and promote the use of low-cost generic drugs.

164. Health plans' inability to detect and prevent such schemes is a practical reality in this industry. Formulary management is just one of many services that health plans hire PBMs to perform. Other services include, for example, managing the network of pharmacies that dispense the drugs to insureds; administering drug utilization and clinical services; overseeing medication adherence programs; and reviewing appeals of any denials of medications. So when a health plan hires a PBM, its services related to formulary management are only a portion of the overall services for which the health plan is negotiating to retain the PBM.

165. Moreover, the negotiations between the health plan and the PBM regarding formulary management cover only *broad*, *aggregate* issues, not the formulary placement, pricing, or treatment of any particular drug. At most, the negotiations address general issues such as the PBM's or the formularies' approach to generic drugs *as a class*, discounts for *all generic drugs* off of price benchmarks, etc.

166. For instance, the health plan may ask how many tiers are included on a PBM's formulary, but that is typically the extent of any discussions regarding formularies. Rather, the PBM promotes the amount of savings the health plan will achieve overall, compared to competing PBMs' offerings. PBMs typically base the projected savings on the health plan's drug utilization from the previous year. If there are any new drug approvals (e.g., the launch of a new generic drug) in the coming year, that information is not even noted in the estimated overall aggregate pricing or savings.

167. Negotiations between health plans and PBMs stay at an aggregate level because, among other reasons, formularies include thousands of drugs. Health plans hire PBMs to develop and manage formularies precisely because the health plans do not have the experience, pharmaceutical or medical expertise, or resources to determine the best tier placement or treatment of each of the thousands of drugs on a formulary. PBMs make those decisions based on industry knowledge and clinical expertise and with the resources necessary to evaluate drug safety and efficacy as well as cost efficiency. If the health plans had that ability, they could forgo hiring a PBM and do the job themselves.

168. Once a contract between the health plan and the PBM is in place, the PBM *unilaterally* adds, subtracts, and places individual drugs on the formulary and on various tiers at

its discretion. The PBM completely controls all these aspects of formulary design and management. And a health plan's contract with its PBM typically extends for three-year terms.

169. During the contract term, PBMs may *unilaterally* update formularies to account for new product launches, indications, clinical evidence, and financial considerations. The PBM can change individual drugs' placement on the formulary tiers, change a drug from preferred to non-preferred, and add or remove prior authorization or step therapy requirements. Health plans are not even aware of, let alone in charge of, how the PBM treats a particular drug on the formulary.

170. PBMs do not share with health plans the details about how or why they determine a particular drug's formulary placement. Nor do standard PBM reports provide sufficient detail to have flagged the placement of generic Tecfidera as a problem. At most, the PBM may provide a report on overall aggregate financial performance, not any information on how a particular drug's placement or treatment affected that performance, or on the PBMs' financial arrangement with a brand-drug manufacturer regarding any particular drug.

171. PBMs closely guard information that would permit health plans, regulators, academics, or any other party to determine whether a PBM is effectively managing and improving generic utilization or is instead disproportionately steering plan participants to drugs that financially benefit the PBM. PBMs erect tremendous roadblocks to prevent plans from knowing the amount of manufacturer payments they secure. Even the most sophisticated buyers are unable to secure specific drug-by-drug manufacturer payment information.

172. Even the "audit" rights in some PBM contracts are illusory. When health plans have attempted to conduct audits, PBMs have responded with intransigence, insisting, for example, that the audit be performed on-site at the PBM's headquarters, that the auditors make no copies of

documents and instead take only handwritten notes, and that the auditors may not report any of the information to the health-plan client.

173. The reality is that no PBM reports provided sufficient detail for health plans to have ferreted out and stopped the Biogen/PBM misconduct with respect to generic Tecfidera. And if any such report had existed, or if any health plan could have conducted an effective audit that might have uncovered this anticompetitive conduct, it would have come after-the-fact, too late to have prevented any health plan from being injured by that conduct.

B. The Perils

174. Health plans rely on PBMs' promises to promote use of generic drugs and to reduce the plans' drug costs. The health plans are vulnerable to PBMs' reneging on those promises at the behest of brand-drug manufacturers.

175. Over the past 20 years, structural economic changes in the PBM marketplace have intensified that vulnerability. The PBM marketplace has become increasingly concentrated. In 2004, the top three PBMs served a combined 190 million people and managed 52% of prescription drug claims. Today, the top three PBMs manage about 80% of prescription drug claims, for about 270 million people. With some overlap among them, the top three PBMs are: CVS Caremark, which manages the claims of 103 million people; ESI, which manages the claims of more than 100 million people; and OptumRx, which manages the claims of over 66 million people. Together with Co-Conspirators Humana and MedImpact, these five PBMs control over 90% of all prescription drug claims.

176. The high concentration of these massive companies is further exacerbated by the concentration in common ownership among them. For instance, the ownership of each of the Big 3 PBM parent organizations (UHG, CVS Health Corporation, and Cigna) includes the same six

companies among their top 10 institutional holders. Together, these six shareholders own 27% to 32% of each PBM parent organization, owning nearly one-third of the companies' combined $819.5 billion market value. And shareholders with shares in four of the five Co-Conspirator PBMs' parent organizations (UHG, CVS Health Corporation, Cigna, and Humana) own 28% of the companies' combined market share. This common ownership reduces competition by diminishing incentives to compete and increasing the ability to share competitively sensitive information.

177. Each of the five Co-Conspirator PBMs has become vertically integrated with various entities along the pharmaceutical supply chain, insulating them from competition by creating barriers to entry for any non-integrated entity that wants to provide competing PBM services. Extensive vertical integration gives them even greater power and control over the distribution and pricing of drugs than their dominance in PBM services alone already provides. Each PBM's vertical integration with pharmacies gives near complete control over the pricing, dispensing, and reimbursement system for all prescription drugs for its covered lives. This control over pharmacy pricing, dispensing, and reimbursement permits the PBM to work with drug manufacturers to drive up drug prices and foreclose patients' access to competitors' less costly drugs. The result is increased profits for the PBMs and brand manufacturers, and higher drug prices for consumers and health plans.

178. This graphic depicts each PBM's vertical integration with midstream distributors, including retail, mail order, and specialty pharmacies. Four of the five are also vertically integrated with a health insurer that controls drug coverage for hundreds of millions of Americans.

Parent/Owner	CVS Health Corporation	The Cigna Group	UnitedHealth Group Inc.	Humana Inc.	MedImpact Holdings Inc.
Drug Private Labeler	Cordavis Limited	Quallent Pharmaceuticals	NUVAILA		
Health Care Provider	MinuteClinic, Signify Health	Evernorth Care Group	Optum Health	CenterWell	
Pharmacy Benefit Manager	CVS caremark 34%	EXPRESS SCRIPTS 23%	Optum Rx 22%	Humana Pharmacy Solutions. 7%	MedImpact 5%
"PBM GPO"/ Rebate Aggregator	Zinc Health Services	Ascent Health Services	Emisar Pharma Services	Ascent (via contract)	Prescient Holdings Group LLC
Pharmacy - Retail	CVS Pharmacy				
Pharmacy - Mail Order	CVS Caremark Mail Service Pharmacy	Express Scripts Pharmacy	Optum Rx Mail Service Pharmacy	CenterWell Pharmacy	Birdi, Inc.
Pharmacy - Specialty	CVS Specialty Pharmacy	Accredo	Optum Specialty Pharmacy	CenterWell Specialty Pharmacy	Specialty by Birdi
Health Insurer	Aetna	Cigna Healthcare	UnitedHealthcare	Humana	

179. Especially relevant here are the "specialty pharmacies" that the PBMs sometimes include in their pharmacy networks. A specialty pharmacy primarily dispenses "specialty drugs" and may be a brick-and-mortar pharmacy or a mail order pharmacy. The vast majority are mail order pharmacies. Historically, specialty drugs were characterized by their need for special handling and administration.

180. Today, however, PBMs exercise unregulated discretion in classifying drugs as specialty medications. Some PBMs designate a drug as specialty based solely on its high cost. When a PBM vertically integrates with a specialty pharmacy, it has an increased ability to steer patients to its own in-house specialty pharmacy and toward more expensive drugs—in exchange for payments from brand manufacturers.

181. The prescriptions having been steered into a limited-distribution channel—shielded from the retail-level competition provided by the nation's tens of thousands of retail pharmacies—the PBMs can and do charge outrageous prices, through their affiliated specialty pharmacies, to patients and health plans for those drugs. It is not unusual for those PBM-affiliated specialty pharmacies to charge prices 20-40 times higher than acquisition costs.

182. Specialty drugs account for a growing share of pharmacy dispensing revenue (about 40-50%) but only a small fraction of total prescription volume (about 2%). A PBM designating a product as a specialty drug may trigger provisions in its contract with a health plan that require the insureds to fill the prescription only at the PBM's affiliated specialty pharmacy. The five Co-Conspirator PBMs' specialty pharmacies account for approximately 70% of all specialty-drug revenue.

183. In 2023, CVS Specialty, owned by CVS Health, earned $73.3 billion in revenues from specialty drugs, which accounted for 30% of all prescription revenues from specialty drugs. Accredo, owned by Cigna/Evernorth, earned $59.5 billion in revenues from specialty drugs, which accounted for 24% of all prescription revenues from specialty drugs. Optum Specialty Pharmacy, owned by UnitedHealth Group, earned $32.3 billion in revenues from specialty drugs, which accounted for 13% of all prescription revenues from specialty drugs. And CenterWell Specialty Pharmacy, owned or controlled by Humana, earned $6.2 billion in revenues from specialty drugs, which accounted for 3% of all prescription revenues from specialty drugs. Overall, mail order pharmacies accounted for more than three-quarters of the industry's $243 billion in total prescription revenues from specialty drugs.

184. Other economic trends in the PBM marketplace confirm that the consolidation and vertical integration in the PBM industry have warped PBMs' incentives, diminished competition

among them, and set the stage for brand-drug manufacturers to cause economic harm to drug purchasers.

185. For example, the PBMs have begun accepting rebates and "fees" from brand manufacturers in exchange for skewing their formularies to favor higher-priced brand drugs over low-cost generic drugs. The brand manufacturers and PBMs win; patients and health plans lose. Similarly, by prioritizing specialty and branded drugs over generics, PBMs can raise drug prices and push consumers toward more expensive options, decreasing the use and availability of lower-cost generics.

186. The PBMs and brand manufacturers, including Biogen, have created a "hide-the-ball" system where the consideration that the manufacturer pays to the PBMs (and does not share with payors) is labeled and relabeled. As more health plans required PBMs to pass a majority of the manufacturer "rebates" through to them, PBMs started renaming the payments in order to keep a larger portion of them. Payments once known as "rebates" are now called administrative fees, volume discounts, service fees, data usage fees, inflation fees, or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

187. The PBMs perform no services for these unearned fees or payments. In return for these fees paid by brand manufacturers, including Biogen, the only thing the PBMs do is disadvantage and suppress lower cost drugs.

188. PBMs have also begun using "rebate aggregators" to negotiate the payments they will receive from the brand manufacturers. Using rebate aggregators allows the PBMs to hide the payments from regulators and the health plans. PBMs have recently doubled the amount of fees they get from drug manufacturers, from $3.8 billion in 2018 to $7.6 billion in 2022.

189. The PBMs carefully guard the revenue streams they receive from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

190. Further reducing transparency, and making oversight more difficult, rebate aggregators affiliated with two of the Co-Conspirator PBMs have been located offshore. Ascent, which contracts with Humana and is owned or controlled by Express Scripts is located in Switzerland. OptumRx located its aggregator, Emisar Pharma Services, in Ireland.

191. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the brand manufacturers tripled, reaching more than $16 billion. That growth in "fees" has continued to accelerate since 2016.

192. In short, health plans cannot defeat the PBMs' accepting of payments from brand manufacturers. Health plans may choose which pharmacy networks and drug formularies to use among the PBM's offerings based on health plan designs, but information asymmetries hinder their ability to make fully informed decisions. So most health plans accept the standard formularies that the PBMs offer or otherwise defer to their PBM's formulary recommendations. Indeed, health plans hire PBMs for their expertise, including in formulary management. See Section V above.

193. From 2016 to 2024, the total revenues of the CVS healthcare conglomerate rose from $177.5 billion to $372.8 billion. Those of the Cigna healthcare conglomerate rose from $39.7 billion to $247.1 billion. Those of the United Healthcare conglomerate rose from $184.8 billion to $400.3 billion, and those of the Humana healthcare conglomerate rose from $54.4 billion to $117.8 billion. They also expanded their operating profits; these four conglomerates' combined profits rose from $14.1 billion in 2016 to more than $24.6 billion in 2024.

194. PBMs began as a partial solution to the problem of brand-drug manufacturers' market power. Formularies and other competitive tools were capable of generating some competition among branded drugs and promoting generic drugs after brand-drug patents expired. But once these commercial behemoths achieved dominance up and down the pharmacy distribution chain, they have proved only too willing to wield that dominance as a mechanism of exclusion at the behest of brand-drug manufacturers. In exchange for payments from the brand-drug manufacturers, the PBMs have thwarted the generic competition that is their legitimate role to promote.

VI. BRAND MANUFACTURERS' ANTICOMPETITIVE TACTICS

195. Over the years, brand manufacturers have developed an arsenal of anticompetitive tactics to impair generic competition. Two are most relevant here.

A. Market Switches

196. One tactic to impair generic competition is to prevent the generic drug from being AB-rated to the brand drug, thereby preventing automatic generic substitution. The AB-rating requirement for generic drugs is designed to ensure therapeutic equivalence to the reference (brand) product. It is concerned only with safety and efficacy, not with effects on competition.

197. Regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A_1, for the purpose of preventing the anticipated generic product from being AB rated to the new brand product. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand

manufacturer can get approval for A_1 and cannibalize the sales of A—use its massive sales force to get doctors to switch their prescriptions from A to A_1.

198. Thus, before the generic of A enters the market the brand manufacturer will have: (a) ensured that the generic product cannot be AB rated to, and substitutable for, A_1; and (b) switched the prescription base from A to A_1. Consequently, when the generic finally gets FDA approval to enter the market, it will garner substantially reduced sales because it is not substitutable for the new brand product to which the brand manufacturer has switched the prescription base.

199. The timing of the switch is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10. Industry analysts in the United States have reached the same conclusion, warning brand manufacturers that it is essential that they switch patients to the new formulation before the generic enters.

200. It is equally well known that, after a market switch, doctors are unlikely to switch back to the original product—in this case, Tecfidera. Having switched their prescribing habits from the original to the reformulated product—and having switched specific patients' medications from the original to a reformulated product—most doctors will not switch their prescribing habits or

their patients back to the original product after the generic is available. In economic terms, switching costs (e.g., the need for another visit to the doctor for a new prescription) impair a move back to the original product. And pharmaceuticals are "experience" goods that consumers and physicians are hesitant to change if they are working.

201. Brand manufacturers know that if they successfully cannibalize the original product's sales before the generics enter the market, the generics are not likely to *ever* compete effectively for those switched prescriptions. Automatic substitution—substitution at the pharmacy counter without doctor approval—is a generic product's only commercially viable means of competing. Once the brand's patents are no longer effective, *no one*—neither the brand manufacturer nor any generic manufacturers—can profitably market the product on a basis other than price. Costs incurred to encourage a doctor to write a prescription for the firm's own product would be squandered because the pharmacist can fill the prescription with a competitor's AB-rated generic product.

202. And this is a good thing. If a manufacturer could profitably market the product to doctors on a basis other than price, this would merely replicate the price-disconnect failure in these markets. The price disconnect is the problem, and AB-rated substitution at the pharmacy counter is the solution. The generic-substitution regime is *designed* to render it unprofitable to actively market the product to doctors.

203. Once the market switch is done, pharmacists are unable to dispense the generic drug through the efficient mechanism of automatic substitution because the dosage form and/or dosage amount is different. Thus, in most instances, the generic's opportunity to compete for those sales is gone forever.

B. Kickbacks to PBMs

204. The recent changes in the PBM industry have set the stage for brand-drug manufacturers to enlist PBMs in impairing rather than promoting generic competition. The vertical integration and market concentration have made it profitable for the PBMs to accept kickbacks from the brand manufacturers to impair generic competition.

205. The basic economics demonstrate why.

206. The brand manufacturer and the PBMs have a collective economic interest in impairing generic competition. If they work together to hinder generic competition, they can keep the profit margins on all the unit sales high and split the resulting excess profits among themselves. They can keep the enormous savings that generic competition would have delivered to drug purchasers. The following series of pie charts demonstrates the brand manufacturer's and PBMs' collective interest in reducing generic competition.

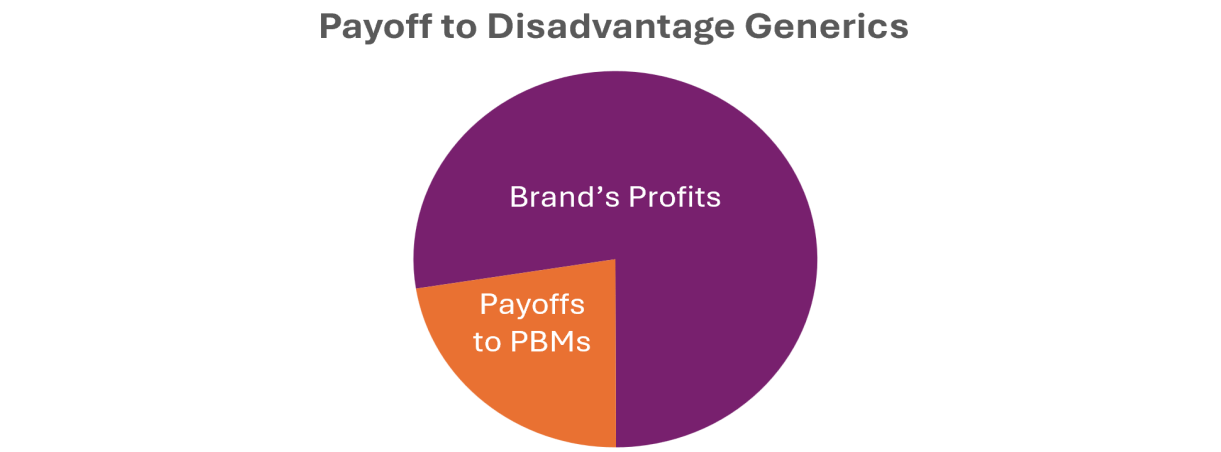
207. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales:

208. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings:

GENERIC COMPETITION DELIVERS SAVINGS TO PURCHASERS

209. To avoid this result, the brand manufacturer can pay the PBM to impair generic competition. The reduced competition keeps the brand manufacturer's profits high, and the manufacturer can use a portion of those extra profits to make the payment to the PBM. The brand manufacturer and the PBM win; the purchasers lose:

PAYOFFS TO PBMS DIVIDE PURCHASER SAVINGS BETWEEN BRAND MANUFACTURERS AND PBMS



210. In order for this anticompetitive pact to work, the brand manufacturer needs a means by which to divide the extra profits with the PBM. The PBM will not help impair generic competition if it does not share in the ill-gotten gains. Kickbacks from the brand manufacturer are the way it divides the ill-gotten gains with the PBM.

211. As explained in detail below (see Sections VIII, IX and X), this case involves a cynical combination of these two generic-impairing tactics—a market switch enabled by kickbacks to the PBMs—together with a host of other Biogen anticompetitive conduct.

212. Biogen paid kickbacks—denominated as rebates and/or fees—to each of the Co-Conspirator PBMs. In exchange, the PBMs agreed not to favor lower cost generic Tecfidera over branded Tecfidera or Vumerity and imposed the same dispensing restrictions on the generic that were applied to the brands. This had devastating financial consequences for health plans and patients.

VII. BIOGEN'S DEVELOPMENT AND SALES OF TECFIDERA AND VUMERITY

A. Multiple Sclerosis Is a Chronic Disease for Nearly One Million Americans.

213. MS is a chronic autoimmune disease that affects the central nervous system. The disease is characterized by the immune system attacking the protective sheath (myelin) that covers nerve fibers, leading to communication problems between the brain and the rest of the body. Almost one million people in the United States have been diagnosed with MS.

214. Although the symptoms and signs of MS can vary, the interruption of signals to the brain generally causes numbness, blindness, mood changes, memory problems, pain, fatigue, and/or paralysis. Other symptoms include lack of coordination, unsteady gait or inability to walk, prolonged double vision, blurry vision, vertigo, slurred speech, and cognitive problems.

215. MS most commonly presents in the relapsing remitting form. Patients will go through cycles of disease flair ups, experiencing symptoms that typically improve fully or partially over time. Remission of the disease tends to follow flair ups, but the length of remission varies.

216. The cost of living with MS is very high. Direct medical costs such as doctor's appointments and the cost of drugs are some of the biggest contributors to the high cost of living with MS. There is no cure for MS.

B. Biogen Made Billions Selling Tecfidera for More Than $90,000 Per Patient Per Year.

217. Biogen is a global biopharmaceutical company that manufactures, promotes, and distributes prescription drugs. On March 19, 2013, the U.S. Patent and Trademark office issued a patent for Tecfidera (dimethyl fumarate). In the same year, the FDA approved Tecfidera for the treatment of MS, and it quickly became one of Biogen's top-selling drugs. Biogen touted Tecfidera's effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions.

218. By 2015, Biogen's U.S. sales for Tecfidera were $2.9 billion, which was nearly half of Biogen's total U.S. product sales ($6.5 billion) for that year. Tecfidera's significant contribution to Biogen's U.S. sales continued throughout the rest of the decade:

Year	Tecfidera US Sales	Total Biogen US Product Sales
2016	$3.1 billion	$7.0 billion
2017	$3.2 billion	$7.0 billion
2018	$3.2 billion	$6.8 billion
2019	$3.3 billion	$6.7 billion

219. Biogen consistently raised Tecfidera's price to increase its total revenue and profits. For example, according to Biogen's 2016 Annual Report, "the increase in U.S. Tecfidera revenues was primarily due to price increases, partially offset by higher discounts and allowances and a decrease in unit sales volume of 1%." Biogen's Annual Reports likewise cited price increases as the reason for increased Tecfidera sales revenue from 2016 to 2017 and from 2018 to 2019.

220. Consequently, as of 2019 the average price of Tecfidera was $124.67 per pill (approximately $90,000 for an annual supply at two pills per day), up from an original 2013 price of about $71.87 per pill (approximately $52,500 for an annual supply at two pills per day)—a 73.5% increase. During that same period, the Consumer Price Index increased by only 9.7%.

221. Health plans allocated substantial financial resources to cover Tecfidera for their members. They assume the financial risk associated with providing healthcare benefits to their employees and members. Outrageously expensive drugs like Tecfidera (and, later, Vumerity) place an enormous financial strain on these plans, including especially the plans sponsored by small-to-mid-sized employers and union health and welfare plans.

222. From 2013 until generic Tecfidera became available in 2020, branded Tecfidera was essentially a must-have for any formulary. It is a life-saving and life-altering drug, so PBMs

had little choice but to include Tecfidera on their formularies. Excluding Tecfidera would have meant denying access to a primary therapy for MS patients.

223. All of that would change when generic Tecfidera became available.

VIII. BIOGEN PAID THE PBMS TO DISADVANTAGE GENERIC TECFIDERA.

224. Biogen paid the Co-Conspirator PBMs to help impede the generic competition that it was their job to promote.

225. Beginning in 2017, Biogen found itself on the defensive as it confronted a series of challenges to its patent on Tecfidera. These patent challenges threatened Tecfidera's patent protections, which Biogen had relied on to secure its market exclusivity and significant revenue streams. Biogen knew that, if the patent challenges succeeded, early entry of generic competition would significantly reduce its profitability from this key product.

226. On June 18, 2020, the U.S. District Court for the Northern District of West Virginia found that Biogen's '514 patent was invalid. The District Court in Delaware reached the same conclusion on September 16, 2020.

227. On August 17, 2020, the FDA approved Mylan Pharmaceutical's ANDA for dimethyl fumarate. Mylan announced the launch of its generic Tecfidera capsules on August 19, 2020. Several additional generic competitors entered the market over the ensuing months.

228. Having lost the legal battle to keep the FDA from approving generic Tecfidera for sale, Biogen turned to keeping generic Tecfidera from actually being sold to buyers.

229. A keystone of that effort was Biogen's paying enhanced rebates and fees to the Co-Conspirator PBMs in exchange for their disadvantaging generic Tecfidera and thereby impairing and delaying generic uptake. Beginning in Spring/Summer 2020, Biogen offered a menu of rebates

and fees calibrated to the degree to which the PBM disadvantaged generic Tecfidera: the more the PBM disadvantaged generic Tecfidera, the more rebates and fees Biogen paid the PBM.

230. Biogen paid the Co-Conspirator PBMs to disadvantage generic Tecfidera in numerous ways, including by placing it on the same or worse formulary tier as Tecfidera; subjecting it to the same dispensing restrictions as Tecfidera; and subjecting it to utilization-management tactics, including step edits or prior authorization requirements. Biogen conditioned the magnitude of the rebates and fees on the PBMs' use of one or more of these anti-generic tactics.

A. Biogen Paid the PBMs to Disadvantage Generics on Formulary Tiers.

231. Biogen paid enhanced rebates and fees to Co-Conspirator PBMs in exchange for their placing generic Tecfidera on the same or worse tier as Tecfidera on the formulary. The payments obscured the price signals received by about 40% of insureds, altogether prevented automatic generic substitution for about 20% of insureds, and disabled mandatory generic substitution laws for another 12+% of insureds.

1. Biogen paid the PBMs to accept and impose the restraints.

232. When generics became available, the PBMs had the unquestioned ability to drive the uptake of generic Tecfidera—or to impair and delay that uptake. Absent some anticompetitive purpose, PBMs promote the lower-price generic substitute for brand drugs. For example, CVS Health's Form 10-K for 2023 states that the company "helps its PBM clients control costs by recommending plan designs that encourage the use of generic equivalents of brand name drugs when such equivalents are available."

233. As noted above, the PBMs' principal way to promote generics is to place them on the lowest (the best) tier on the formulary—Tier 1. Correspondingly, the PBMs place the counterpart brand drug on the highest (the worst) tier—Tier 5.

234. Tier placement is important because, among other things, it determines the copayment or coinsurance that the insured must pay out of pocket. Those requirements provide price signals, which are essential to the proper functioning of markets. Copayments and coinsurance provide price signals to insureds, giving them economic incentives to properly weigh relative costs when choosing which drug product to buy. The copayment and coinsurance price signals thereby help to efficiently allocate society's scarce resources.

235. **Of course** a PBM that has not been paid off will promote the generic. Generics sell at a small fraction of the brand's price. Here, within seven months of entering the market the generics were selling for $14 per pill while brand Tecfidera was $132 per pill.

236. Biogen paid each of the five PBMs (and others) to not promote or advantage generic Tecfidera over brand Tecfidera or Vumerity. It paid increased rebates and fees to PBMs if they agreed not to place the generics on a better tier than branded Tecfidera and Vumerity.

237. The PBMs passed *some* of the *rebates* on to *some* of their customers. They did not pass on any of the relevant unearned *fees*, which account for a substantial portion of the total kickbacks.

238. The PBMs are not buyers of Tecfidera, Vumerity, or the competing generic products. The PBMs negotiate formulary placement and prices on behalf of the health plans and the insureds. In paying the rebates and fees to the PBMs, Biogen was not competing with generic Tecfidera on price. Biogen paid the PBMs to impair that competition and to give Biogen time to conduct the market switch.

239. This is confirmed empirically by the basic economics. In 2022 the average cost for pharmacies to acquire generic Tecfidera was just $10 per pill. In contrast, Biogen's average rebates and fees (combined) on branded Tecfidera—even if they had been fully passed on by the PBMs to

their health-plan clients—would have resulted in a net price of $101 per pill. That is more than 1,000% greater than the generic price. Biogen was not competing on price to win the health plans' business. It was paying the PBMs to undermine the generic competition that it was their job to promote for the benefit of their health plan clients.

240. The conclusion is no different when examining retail prices rather than acquisition cost. For example, in 2022 the typical retail price for generic Tecfidera (real generics, not the generics that Biogen paid to have marketed as "specialty") was about $25 per pill, versus an average net price—even if all rebates and fees had been passed on to the health plans—of $100 per pill for brand Tecfidera. The net price of Tecfidera at retail was 400% more than the generics. Notably, the average retail prices for generic Tecfidera were artificially increased by Biogen's manipulation of the formularies. Pharmacies that sold generic Tecfidera outside the PBM ecosystem—pharmacies like Mark Cuban's Cost Plus Drug Company—charged a retail price of only $1 per pill.

241. Biogen's rebates and fees were payments *to the PBMs* in exchange for impairing the generics, not price reductions to the health plans that, even if fully passed on to them, would have produced savings anywhere near what the generics offered. The rebates and fees were not competitive price reductions to health plans; they were kickbacks to the Co-Conspirator PBMs in exchange for their help in impairing competition.

242. That conclusion is further reinforced by the change in the amount of rebates/fees that Biogen paid based on the *timing* of its market switch. Biogen paid the highest rebates/fees on Tecfidera in the key year 2021 as it worked feverishly to switch the market from Tecfidera to Vumerity. The average rebates/fees rose from 12% of the list price in 2019, to 19% in 2020 (the generics did not enter until Fall 2020), to the *high point of 45% in 2021*, and then declined to 28%

in 2022, and 27% in 2023. Biogen was paying the PBMs for their help in making the market switch; it paid the highest rebates/fees in the year that it most needed their help to impair generic competition and make the switch.

243. Biogen was not paying these rebates/fees to win the health plans' business by competing with generic Tecfidera on price. If Biogen had been doing that, the list price of Tecfidera minus all rebates/fees would have been close to the price of generic Tecfidera and would have declined as the price of generic Tecfidera declined. That is not at all what happened.

244. Instead, the list price of Tecfidera minus all rebates/fees fell from $115 per pill in 2019, to $112 in 2020 (the generics did not enter until Fall 2020), to the *low point of $75 in 2021*, and then *rose* substantially to $100 in 2022, and $110 in 2023. In contrast, the retail prices of generic Tecfidera—the real generics, not the generics that Biogen paid to have marked as "specialty" generics—were dramatically lower, and they substantially *and steadily* decreased over time. They did not, as Biogen's net prices did, increase after the critical year 2021. They continued to substantially decline.

245. If Biogen were competing on price for the health plans' business, it could have simply offered them a low net price. Biogen and the PBMs decided to use "rebates" and fees rather than offer low net prices to the health plans and insureds. And even if Biogen had some unknown but legitimate reason to use rebates and fees rather than a low net price, it made the choice to pay the rebates and fees to the PBMs rather than to the health plans. Biogen paid rebates and fees to the PBMs because it was paying them off to help impair the generic competition that it was their proper role to promote.

246. And the PBMs knew that Biogen was using the competition-impaired time that it bought from them to switch the market from Tecfidera to Vumerity. The PBMs did not initially

favor Vumerity over Tecfidera on their formularies. If Vumerity had medically significant advantages over Tecfidera, in terms of clinical effectiveness or patient tolerability, the PBMs would have placed Vumerity in a superior position on their formularies as soon as Vumerity was available. They did not.

247. The PBMs participated in the anticompetitive scheme and actively facilitated it because Biogen handsomely paid them to do so.

2. The restraints obscured price signals and impaired generic uptake as to a substantial volume of commerce.

248. The data help to gauge the magnitude of the anticompetitive effects that this aspect of Biogen's conduct caused.[2] For example, in the key first calendar year of generic Tecfidera entry, 2021, Biogen paid the Co-Conspirator PBMs to disadvantage generic Tecfidera on formularies covering about 40% of insureds.

249. This chart lists the PBM, the year, and the percent of insureds on the PBM's formularies that placed the dramatically lower-cost generic Tecfidera on the same or worse tier than branded Tecfidera:

PBM	2021	2022	2023	2024
CVS Caremark	33%	35%	39%	31%
Express Scripts	40%	13%	14%	21%
OptumRx	43%	39%	35%	19%
Humana	69%	94%	74%	27%
MedImpact	34%	37%	32%	28%
All Five PBMs	39%	33%	33%	24%

250. Every one of these affected buyers of dimethyl fumarate received a false price signal as to the relative costs of generic Tecfidera and Tecfidera. The anticompetitive effects of

[2] Managed Markets Insight & Technology, LLC, is the source for many of the formulary data summaries alleged herein.

obscuring these price signals are obvious and substantial. In a related context, the federal government has concluded that obscuring or eliminating these price signals anticompetitively "eliminat[es] a market safeguard against inflated prices." Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005). *See* Section IX(A) below for more details.

251. Biogen's scheme obscured price signals even as to the relatively modest percentage of insureds who paid coinsurance—a percentage of the drug's cost—rather than a copayment for Tecfidera and generic Tecfidera. Those insureds typically paid coinsurance only up to a capped amount per prescription; the cap was the same for brand and generic drugs; and the cap was typically less than the insured would otherwise owe in coinsurance for the high-priced "specialty" generic Tecfidera. So the insured would pay the same amount in coinsurance for Tecfidera or the specialty generic Tecfidera.

252. In addition, the vast majority of insureds who paid coinsurance for these drugs were required to pay only up to a maximum total amount per year. Biogen paid the Co-Conspirators to put generic Tecfidera on the same, higher tiers as Tecfidera, so these insureds reached their annual maximums sooner. And even when these insureds were still subject to paying coinsurance, Biogen implemented another tactic—discussed in Section IX(A) below—to obscure or eliminate price signals to them.

253. In addition to impairing or eliminating price signals, Biogen's payments altogether disabled automatic generic substitution for a substantial portion of the relevant sales. Many state generic-substitution laws prohibit the pharmacist from automatically substituting the generic product for the corresponding brand product unless the patient will pay *less*—not merely the same—for the generic.

254. The chart attached as Appendix A identifies the states whose laws prohibit automatic substitution unless the patient pays less for the generic. About 48.8% of the U.S. population lives in those states. Biogen's payments to the PBMs prevented generic substitution in those states.

255. Other states require the pharmacist to substitute the generic. But 14 of these mandatory-substitution states— Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin—mandate generic substitution only if the patient will pay less for the generic. *See* Fla. Stat. § 465.025(2); Haw. Rev. Stat. § 328-92 (a); K.R.S. 217.822(1), (3); Mass. Gen. Laws ch. 112, § 12D; M.S.A. § 151.21(3), (4); Nev. Rev. Stat. § 639.2583(1), (3); N.J. Stat. § 24:6E-7; N.Y. Educ. Law § 6810 6(a), (c); N.Y. Educ. Law § 6816-a; 35 Pa. Stat. § 960.3(a); R.I. Gen. Laws § 5-19.1-19; R.I. Gen. Laws § 5-37-18.1; R.I. Gen. Laws § 21-31-16.1; Tenn. Code § 53-10-204(a); Tenn. Code § 53-10-205(a); VT ST. T. 18 § 4605; W. Va. Code § 30-5-12b; Wis. Stat. Ann. § 450.13.

256. About 30.8% of the U.S. population lives in these states. Biogen's payments to the PBMs wholly disabled mandated substitution in these states.

257. Altogether, about 79.8% of the U.S. population lives in states where Biogen's payments to the Co-Conspirators not only affected price signals to the insureds, but directly triggered provisions in state generic-substitution statutes, either altogether prohibiting automatic substitution or disabling mandated substitution.

B. Biogen Paid the PBMs to Designate the Generics as a Specialty Drug.

258. Biogen paid enhanced rebates and fees to Co-Conspirator PBMs in exchange for their subjecting generic Tecfidera to the same dispensing restrictions as Tecfidera. Each of the PBM Co-Conspirators had previously designated Tecfidera (and Vumerity) as specialty drugs and required that they be dispensed through specialty pharmacies, including through the specialty pharmacies that the Co-Conspirator PBMs owned or controlled. The payments dramatically raised the price of generic Tecfidera and slowed its uptake. They had that effect for more than 60% of insureds.

1. Biogen paid the PBMs to accept and impose the restraints.

259. To get the enhanced rebates and fees that Biogen offered in exchange for imposing the same dispensing restrictions on generic Tecfidera, Biogen required that the PBMs that had designated Tecfidera as a specialty drug apply that same designation and set of restrictions to generic Tecfidera.

260. Nothing about Tecfidera required special handling—it is a shelf-stable pharmaceutical dispensed in pill format. Instead, the PBMs had designated Tecfidera as a specialty drug based on its astronomical price.

261. That rationale did not apply to *generic* Tecfidera. It was available for a small fraction of the wholesale price of Tecfidera. And, like Tecfidera, the generics were shelf-stable pills that provided no *medical* rationale for being designated a specialty drug. If such a medical rationale had existed, the generics would have been designated a specialty drug on nearly *all* formularies.

262. The purpose and effect of Biogen's requiring that designation was to make patients incur a very high copayment or coinsurance for generic Tecfidera, significantly reducing their

incentive to accept the generic. Another purpose and effect was to require that the falsely designated product be dispensed only through a small number of specialty pharmacies, shielding those pharmacies—owned by the PBMs—from price competition from all other pharmacies. Biogen knew and intended that this would substantially depress the sales of generic Tecfidera by keeping its price to health plans and other purchasers astronomically high.

263. The high market concentration and extensive vertical integration that characterize the PBM industry ensured that competition among the PBMs would not dissuade any one of them from designating generic Tecfidera as a specialty drug. All five Co-Conspirator PBMs are affiliated with a specialty pharmacy; all five shared a desire—absent effective competition among them—that its specialty pharmacy make these outlandish profits on the sale of generic Tecfidera; and each of the five knew that Biogen was offering the same kickbacks to the other four.

264. Indeed, the PBM-affiliated specialty pharmacies bought generic Tecfidera from the manufacturers for as little as $180 for a 30-day supply; they sold it to the health plans and their insureds for as much as $3,857.

265. The artificially high price that the PBM-affiliated specialty pharmacies charged to health plans for generic Tecfidera also had the intended effect of making the prices of branded Tecfidera and Vumerity appear to be more reasonable than they were. The artificially high price of the generic made the price of branded Tecfidera and Vumerity—plus some share of rebates—seem like a better deal than it really was for health plans and insureds.

266. If generic Tecfidera had been available to the health plans *at a competitive price*—for, say, $3 per pill rather than the artificial $64 per pill through the specialty pharmacy—health plans would have seen the prices of branded Tecfidera and Vumerity (even with some share of the rebates) as the rip-off that they were.

267. The artificially high price of generic Tecfidera through the specialty pharmacies had the effect that Biogen intended. It resulted in continued inflated sales of branded Tecfidera and Vumerity at supracompetitive prices. The PBMs went along with the anticompetitive scheme because Biogen paid them to.

2. The restraints directly raised prices and impaired generic uptake as to a substantial volume of commerce.

268. Biogen's payments in exchange for the specialty-drug designation worked. Two cohorts of insureds were affected by Biogen's payments in exchange for designating generic Tecfidera as a specialty drug. One cohort was covered by a formulary that had a specialty drug tier. The other cohort was covered by a formulary that did not have a specialty drug tier, but Biogen nevertheless paid the PBMs to designate generic Tecfidera as a specialty drug and require that it be purchased through a specialty pharmacy.

269. In 2021, substantially less than half of insureds were covered by a formulary that had a specialty drug tier. About 17% of *all* insureds—40% or more of those covered by a formulary that had a specialty-drug tier—were subject to a formulary that put generic Tecfidera on that tier.

270. More than half of insureds were covered by a formulary that in 2021 did not have a specialty drug tier. But Biogen's payments-for-impairing-generics scheme extended to them too. Where the formulary did not have a specialty drug tier, Biogen nevertheless offered rebates and fees, and Co-Conspirator PBMs accepted them, in exchange for designating generic Tecfidera as a specialty drug, thereby requiring that it be dispensed through a specialty pharmacy. Biogen's payments in exchange for the specialty designations resulted in half or more of this cohort of insureds being required to buy "generic" Tecfidera through the specialty-drug channel.

271. Altogether, Biogen's payments to the PBMs for designating generic Tecfidera as a specialty drug resulted in about 60% or more of all insureds paying the outrageous thousand-dollar specialty-drug prices for a generic drug that was otherwise available for less than a tenth of that.

272. Moreover, a substantial number of insureds were not subject to the specialty-drug designation but were nonetheless affected by Biogen's payments to the PBMs to disadvantage generic Tecfidera in its formulary-tier placement relative to branded Tecfidera and Vumerity. At least 75% of all insureds were subject to either the specialty-pharmacy designation, the improper tier placement, or both.

C. Biogen Paid the PBMs to Impose Step Edits and Prior Authorizations on Generic Tecfidera.

273. Biogen paid enhanced rebates and fees to Co-Conspirator PBMs in exchange for their using "utilization management" techniques against generic Tecfidera. The purpose and effect of those techniques was to substantially impair the sale of generic Tecfidera. The payments subjected more than 68% of insureds to formularies that placed generic Tecfidera on a tier other than Tier 1 and/or that imposed a step edit or prior authorization on generic Tecfidera.

1. Biogen paid the PBMs to accept and impose the restraints.

274. Two of the utilization-management techniques that Biogen paid the PBMs to use against generic Tecfidera were "step edits" and "prior authorizations." With a step edit the PBM requires the insured to fill a prescription for some other drug before it will cover the drug that is the subject of the step edit.

275. For example, a PBM might legitimately require the insured to first try—use as a first "step"—a more effective drug, or an equally effective but less expensive one, before getting the targeted drug.

276. But Biogen's payment for a step edit against generic Tecfidera was wholly illegitimate and anticompetitive. Even when generic Tecfidera was nominally on the first (best) tier of the formulary, Biogen paid enhanced rebates and fees to PBMs to use a step edit that required insureds to first try another MS drug—including sometimes requiring that they first try Tecfidera or Vumerity—before becoming eligible for coverage of generic Tecfidera.

277. Biogen also paid the PBMs to require "prior authorization" before the insured could purchase generic Tecfidera. This requirement mandated that the patient's doctor make a formal request to the PBM to approve coverage of generic Tecfidera. Again, in other circumstances prior authorization requirements might play a legitimate role. Their only role here was to delay and impair the uptake of the dramatically less expensive generic Tecfidera.

278. PBMs originally developed these utilization-management techniques in order to engender price competition among similarly high-priced branded alternatives within a therapeutic class. Here, Biogen wielded these techniques *against* price competition—paying PBMs to promote the high-price brands over the much-lower-priced generics.

2. The restraints impaired generic uptake as to a substantial volume of commerce.

279. Like the other Biogen/PBM anticompetitive restraints, these anti-generic tactics were widespread. For example, Biogen paid the Co-Conspirator PBMs to place generic Tecfidera on a tier other than Tier 1 and/or to impose step edits or prior authorization requirements on generic Tecfidera on formularies covering about 68% of insureds.

280. Of particular note is that, absent the payments from Biogen, no legitimate rationale can explain why a PBM would forgo placing generic Tecfidera—a drug available at massive

discounts off the price of the brand—on the lowest tier, with no roadblocks like step edits or prior authorizations. Yet Biogen's payments overturned that competitive outcome.

281. This chart lists the PBM, the year, and the percent of insureds on the PBM's formularies that placed generic Tecfidera on a tier other than Tier 1 and/or imposed the paid-for step edits or prior authorizations on generic Tecfidera:

PBM	2021	2022	2023	2024
CVS Caremark	68%	69%	66%	62%
Express Scripts	54%	60%	44%	46%
OptumRx	87%	86%	82%	82%
Humana	98%	96%	93%	95%
MedImpact	50%	50%	44%	41%
All Five PBMs	68%	71%	64%	61%

282. In the years 2021 to 2024 generic Tecfidera should not have been placed above Tier 1, or with restrictions, on formularies covering *any* insureds—it should not and would not have happened. Instead, Biogen paid for a *substantial majority* of insureds to be subjected to one or both of those disadvantages. From 2021 to 2024 the percentage of insureds who were subjected to those restraints were 68%, 71%, 64%, and 61%, respectively.

283. Again, there is not complete overlap between the insureds who were subjected to these utilization-management techniques and those who were subjected to one or both of the relative-tier and specialty-pharmacy aspects of Biogen's scheme. In total, well more than 75% of insureds were affected by one or more of the improper tier placement, specialty-pharmacy designation, or utilization-management aspects of Biogen's scheme.

284. The other 25% (or less) may have been only indirectly affected by Biogen's offers to pay the PBMs. But that is not the result of health plans' decisions specifically regarding generic Tecfidera. Instead, the PBMs, not the health plans, made the decisions whether, and to what extent, to accept Biogen's payments in exchange for disadvantaging generic Tecfidera.

285. The PBMs made those decisions based on their own financial goals. PBMs have detailed information regarding the current and expected drug usage for each particular health plan that it manages. So PBMs can and do accept or decline rebate and fee offers from brand drug manufacturers to maximize the PBMs' profits on a plan-by-plan basis.

286. A variety of considerations (e.g., the number of plan members who take the drug, rebate offers from other brand manufacturers, and the margin that the PBM's specialty pharmacy made on the drug) affected the PBMs' analyses as to whether and to what extent to accept Biogen's payments with respect to particular plans. The PBMs, not the health plans, made those decisions. The fact that the PBMs made different decisions with respect to different health plans does not imply otherwise.

IX. BIOGEN USED PATIENT COUPONS TO UNDERMINE PRICE SIGNALS AND IMPAIR GENERIC UPTAKE.

287. Biogen also delayed and impaired competition from generic Tecfidera by undermining the incentives that some formularies put in place to encourage insureds to buy the generics. Thus, even when Biogen had not succeeded in paying to rig a formulary against generic Tecfidera, Biogen still anticompetitively undermined insureds' incentives to choose the dramatically lower-cost generics.

288. Biogen undermined those incentives by offering to pay the copayments or coinsurance of Tecfidera patients, thus falsely making generic Tecfidera appear to be more expensive than Tecfidera. Biogen made the copayment/coinsurance "coupons" available to all Tecfidera patients, and some 33% likely used them.

A. Using Patient Coupons to Undermine Incentives for Buying Generics is Anticompetitive.

289. Requiring that insureds pay a copayment or coinsurance helps to align the insureds' economic interests and incentives with those of the health plans. Insureds, not the health plans, decide which prescription drugs to purchase, but the health plans pay the vast majority of the cost. Copayment and coinsurance requirements make insureds more sensitive to price.

290. Simply put, an insured is more likely to buy a generic drug for which she pays a $20 copayment than the brand-drug version with a $50 copayment. The same is true for an insured who must pay 20% coinsurance for a $75 generic rather than a $300 brand drug. These cost-share obligations provide essential price signals for insureds to properly weigh relative costs, allowing market forces to determine which products are bought, and at what price.

291. Biogen undermined these price signals and economic incentives for insureds in private health plans (not Medicare or Medicaid), even when it had not otherwise already rigged the formularies against generic Tecfidera. Instead of competing with generic Tecfidera on price, Biogen devised a scheme to bypass the price signals that would have prompted insureds to select generic Tecfidera.

292. Biogen gave "coupon" cards to insureds that eliminated the copayments and coinsurance that otherwise would have guided them to appropriately consider price when choosing between Tecfidera and generic Tecfidera. Generic manufacturers generally cannot provide patient coupons. Generic drugs are commodities, and a manufacturer that issued a coupon for using a generic version of a drug could not ensure that the coupon would be used to buy its version rather than a competitor's. And generic manufacturers' generally thin margins could not support such a program in any event.

293. Except presumably in states that prohibit such coupons (California and Massachusetts), Biogen made the coupons available to *all* insureds with private health-plan coverage who had been prescribed Tecfidera. Insureds' eligibility for the coupons did not depend on their ability to pay or other need-based criteria. Biogen ensured that the coupons would eliminate price signals that *all* of these private-plan insureds otherwise would have received as to the relative costs of generic Tecfidera versus Tecfidera.

294. Under the Biogen scheme, pharmacies accepted the Biogen coupons from the insureds in lieu of collecting the otherwise required copayment or coinsurance. Biogen then reimbursed the pharmacy for the value of the coupon. The insureds could receive Tecfidera, having paid little or nothing out of their own pockets. Generic manufacturers cannot economically provide such coupons, so Biogen's scheme arranged for insureds who used the coupons to actually pay *less* for Tecfidera than they would have paid for the less expensive generic Tecfidera.

295. Biogen shielded coupon-users from the small fraction of the product's total price that they paid. By doing so, Biogen ensured that those who pay the vast majority of that price—the health plans that are Plaintiffs and Class members here—paid the outrageously high prices for Tecfidera.

296. These anticompetitive effects are so substantial and obvious that the federal government has outlawed the use of such coupons with respect to federal drug-benefit plans. A 2005 Advisory Bulletin from the Department of Health and Human Services, Office of Inspector General explained:

> Subsidies provided by traditional pharmaceutical manufacturer PAPs [patient assistance programs] have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives) ....

> [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.

Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005).

297. The Bulletin concludes that these coupons "eliminat[e] a market safeguard against inflated prices." *Id*. Therefore, the federal Anti-Kickback Statute prohibits their use by Medicare recipients. 42 U.S.C. § 1320a-7b(b). For similar reasons, California and Massachusetts prohibit coupons, even in private health plans in those states, when a generic version of the drug is available.

298. A prominent Stanford health-policy researcher, whose specialties include empirical research on drug prices, concluded that these coupon programs "effectively counteract health plans' efforts to encourage patients to choose less expensive alternatives by placing them in formulary tiers with lower cost sharing . . . These programs have driven a wedge between the perceived interests of patients and those of their health plans. They are highly effective in inducing prescriptions for branded drugs: in one study, they increased branded-drug sales by sixty percent, with commensurate reductions in sales of generic drugs." Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?,* 102 Minn. L. Rev. 2273, 2291 (2018).

299. Congressional investigators with access to some brand manufacturers' internal documents similarly confirmed that these patient coupon programs are anticompetitive, especially when used in the face of generic competition. The investigators "obtained internal discussions and strategy documents in which companies … emphasized the rates of return of their copayment

assistance programs for commercial patients. Internal [company] documents emphasized that its copayment program encouraged patients to stay on branded [drug] even after the entry of generic competition." *Drug Pricing Investigation*, Committee on Oversight and Reform, U.S. House of Representatives, Majority Staff Report (Dec. 2021).

300. The brand manufacturers use the coupons as "public relations tools," but their internal documents "emphasized the significant returns on investment from these programs in the form of increased sales, particularly for drugs approaching loss of exclusivity." *Id*. at xiv. "Internal documents indicate that enhanced copay programs were a crucial piece of [the brand manufacturer's] loss-of-exclusivity strategy for [the brand drug], encouraging patients to stay on the branded drug even after generic entry." *Id*. at 157. The manufacturers' documents showed a huge return on investment—from 450% to nearly 900%—in the coupon programs, as they substantially muted generic uptake. *Id*. at 154, 157.

B. The Coupons Impaired Generic Uptake as to a Substantial Volume of Commerce.

301. Biogen wielded the anticompetitive coupon tactic with respect to insureds in private health plans that are not subject to the Anti-Kickback statute. About 33% of insureds on specialty medications typically use available copay/coinsurance coupons. Given the astronomical price of Tecfidera, and the absence of income eligibility limitations on receiving the coupons, the percentage here is likely higher.

302. Combined, Biogen's various tactics applied to well more than 75% of insureds—likely closer to 90% or more. And they worked cumulatively and synergistically to prevent purchasers from obtaining the benefits of generic competition that the law provides.

303. To take but one example of the tactics' combined effect, Biogen paid the PBMs to require step edits and prior authorizations. State mandatory substitution laws (see Section XIII(A) above) might have overcome those Biogen/PBM-imposed requirements, mandating that the pharmacist dispense generic Tecfidera when presented with a prescription for Tecfidera. But Biogen disabled those state laws by also paying the PBMs to charge equal copayments for the brand and generic.

X. BIOGEN ANTICOMPETITIVELY SWITCHED THE MARKET FROM TECFIDERA TO VUMERITY.

304. When entry of generic Tecfidera became imminent, Biogen took affirmative, costly steps to destroy the market for Tecfidera and its generics, effectively coercing physicians to prescribe, and patients to take, Vumerity.

305. One purpose of Biogen's impairing competition from generic Tecfidera, through the many tactics described above, was to buy time to switch the market from Tecfidera to Vumerity. Generic Tecfidera is not AB-rated to Vumerity, so it cannot be automatically substituted. Biogen's switching the market from Tecfidera to Vumerity had the purpose and effect of permanently shielding a substantial portion of the fumarate prescription base from automatic generic substitution.

306. To switch the market to Vumerity, Biogen used a toxic brew of anticompetitive tactics. These included: (a) concocting and pervasively marketing the false claim that Vumerity is medically superior to Tecfidera; (b) paying the PBMs to place generic Tecfidera on the same formulary tier as Vumerity; (c) using patient coupons to make Vumerity appear less costly than generic Tecfidera; (d) linking rebates and fees on Tecfidera to better formulary placement of Vumerity; and (e) directly reducing the supply of generic Tecfidera.

307. The scheme brought massive monopoly profits to Biogen and commensurately massive losses to Plaintiffs and other buyers of fumarate. In competitive conditions, Vumerity would have achieved less than a 5% share of the unit sales of fumarate. Instead, Biogen's anticompetitive scheme brought that share to more than 25%, costing fumarate buyers more than $655 million per year. Those losses are ongoing.

A. Biogen Developed an "Evergreen" Strategy for its Fumarate Franchise.

308. Biogen developed a plan to "evergreen" its fumarate franchise by moving the Tecfidera prescriptions to a follow-on product. That product was Vumerity (diroximel fumarate). The development journey of Vumerity began with a U.S. patent application submitted in September 2013 by Alkermes plc, a Dublin-based pharmaceutical firm. This patent was issued on March 31, 2014 and expires on October 29, 2033.

309. Alkermes developed the formulation of diroximel fumarate in partnership with Biogen. Despite this early start in development, Biogen did not file an NDA for diroximel fumarate until December 2018. The FDA granted approval for the drug in October 2019.

310. Biogen got FDA approval of Vumerity by using the studies that showed that *Tecfidera* was safe and effective. Biogen submitted studies showing that Vumerity is bioequivalent to Tecfidera.

311. Vumerity is diroximel fumarate, while Tecfidera is dimethyl fumarate. Although diroximel fumarate and dimethyl fumarate have different chemical structures and pharmacokinetic properties (how they are absorbed, distributed, and eliminated), the body rapidly converts both of them to the same active ingredient—monomethyl fumarate. It is that active ingredient that provides the drugs' therapeutic effects.

312. Similarly, the dosing regimens for the two medications share a common therapeutic strategy, which involves starting the patient on a lower dosage before escalating to a higher maintenance dose. A lower starting dosage allows the body to adjust to the new medication. Each Vumerity pill is 231mg. To start, the patient takes one pill (231mg) twice a day orally for 7 days. After 7 days, the patient increases the dosage to 2 pills (462mg) twice a day orally for maintenance. The Tecfidera starter pack includes pills that are 120mg each. To start, the patient takes one pill (120mg) twice a day orally for 7 days. After 7 days, the patient starts the maintenance dosage. This dosage contains pills that are 240mg each. And the patient takes one pill (240mg) twice a day orally for maintenance.

313. Amid the uncertain climate of ongoing patent litigations for Tecfidera, Biogen told its investors that, if the Tecfidera patent was invalidated, it could switch the market to Vumerity. Biogen underscored this point, stating to investors that, "Importantly, ahead of the outcome of the IPR and District Court and the Litigations, we shall have the opportunity to launch VUMERITY, a novel oral fumarate disease-modifying treatment that has the potential to be another important choice for MS patients." Biogen explained that "[i]t is a priority that we appropriately maximize the potential of VUMERITY."

314. During that same investor call, an analyst asked, "Am I hearing it correct and also should we reasonably expect a meaningful switch ahead of IPR decision?" Biogen's CEO responded, "So from day one and this is the reason why we did the—we deployed capital and acquired this asset [the license from Alkermes] is that it was meaningful and strategically important for the company."

315. A month later, the CEO again told investors that "obviously, the patent situation will certainly have an entrance into the tactical plan of launching VUMERITY. But for that, we

are working hard and time will tell, okay? The important situation, again, is that VUMERITY will be launched months or quarters before the court ruling on the [Tecfidera] IP."

316. Biogen later advised its investors that, "if we're unsuccessful with either the two district court cases, we've got VUMERITY as a product that we can kind of look at, is a fumarate strategy that we're looking at."

1. Biogen's Sole Motive Was to Impair Generic Tecfidera.

317. Biogen's sole motive in developing and marketing Vumerity was to use it in the evergreening strategy to defeat competition from generic Tecfidera. That exclusionary motive is confirmed by the fact that the strategy made economic sense for Biogen only because it had the effect of impairing generic competition. Biogen's decision to incur the extra costs (and suffer the revenue losses) associated with switching the market from Tecfidera to Vumerity was economically rational only because the switch had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Biogen would not have invested the resources necessary to reformulate and cannibalize Tecfidera because doing so would have been a money-losing proposition.

318. Biogen knew when it was planning the switch that its combined sales of Tecfidera and Vumerity would be far less than its sales of Tecfidera before the switch. And as events played out, Biogen's forecast was correct.

319. But Biogen also knew that the combined sales of Tecfidera and Vumerity would be far greater than sales of Tecfidera alone following generic entry. The market switch would have the intended effect of shielding from generic competition all the prescriptions that Biogen managed to switch from Tecfidera to Vumerity before generic Tecfidera entered the market.

320. Biogen incurred very substantial costs to garner these reduced sales. Biogen spent significant sums to develop Vumerity, obtain a patent that purportedly protected it, gain FDA approval, promote the product, and make royalty payments to Alkermes. Under the terms of their operating agreement, FDA approval triggered a clause in which Biogen paid Alkermes $150 million for the worldwide commercial rights to Vumerity, along with 15% royalties on all sales.

321. If the switch did not have the effect of impairing generic competition, the switch would have been a money-losing proposition for Biogen. The conduct made economic sense for Biogen solely because it did have the effect of impairing generic competition. Biogen's investments in reformulating and cannibalizing the sales of Tecfidera were not investments in improving products and helping patients; they were investments in impairing competition.

2. Biogen Pulled "All Levers" to Support the Market Switch.

322. Biogen launched Vumerity in October 2019. As noted above (Section VI(A)), a market switch is most successful if the brand manufacturer switches the market from the original product to the new product before generic versions of the original product enter the market. Biogen thought it would have time to switch the market because it thought it could settle the patent litigation over generic Tecfidera with agreements by the generic manufacturers to delay entering the market until years later. That would give Biogen plenty of time to get doctors to switch from Tecfidera to Vumerity. In July 2019, Biogen told its investors that "there was a lot of interest" in settling the patent litigations.

323. Biogen's confidence that it could get delay through settlements was misplaced. It was unable to reach settlements with Mylan and other generic manufacturers before those cases went to trial. Biogen's patent was so weak that the generic manufacturers were not willing to settle the litigation by accepting long delays in entering the market. So the bench trial in the Delaware

case went forward in December 2019, and the bench trial in the West Virginia case proceeded in February 2020. Both courts found the patent invalid.

324. After the first decision, in July 2020, Biogen advised investors that "[g]oing forward, our strategic focus is now on VUMERITY, and we are increasing our resource allocation to maximize this next-generation fumarate." The CEO emphasized that "now the entire focus is pivoting on VUMERITY…." Biogen was making "a significantly enhanced focus of the organization on one brand, VUMERITY."

325. Biogen's Executive VP & Chief Medical Officer had told investors in 2019 that "physicians that I talked to would not want to switch somebody who's done well who's stabilized [after] the initial phases of taking TECFIDERA and are doing well in terms of tolerability." But Biogen abruptly changed its position once competition from generic Tecfidera was imminent.

326. Biogen started using its army of sales force detailers to cannibalize the Tecfidera prescriptions, i.e., to aggressively switch them to Vumerity. Among many other marketing tactics, Biogen implemented "incentive schemes" for its salesforce, conditioning top pay to converting as many Tecfidera prescriptions as possible to Vumerity.

327. Even after losing both of the patent cases in the district courts, Biogen thought it still had time to switch the market to Vumerity before the entry of generic Tecfidera. When the brand drug has sales of the magnitude that Tecfidera achieved—more than $3 billion annually—generic manufacturers will sometimes wait to enter the market despite a win in the district court. They wait until their trial-court victory is affirmed on appeal. If they enter the market and the patent victory is later overturned on appeal, they are liable to the brand manufacturer for patent infringement. On a drug like Tecfidera, the patent-infringement damages can be very substantial, and generic manufacturers are not always willing to take that kind of risk.

328. Accordingly, Biogen told its investors in July 2020—after Biogen's first loss to a generic manufacturer at trial—that Biogen "assumed no generic entry for Tecfidera" in 2020. But Biogen's planning was wrong again. Its patent was so weak that the generic manufacturers did not wait for an appellate decision affirming invalidation of the '514 Patent before entering the market.

329. Biogen's plans to further delay the entry of generic Tecfidera were in shambles. So it turned to implementing a multiple-tactic scheme to minimize generic Tecfidera sales while it worked to switch the market to Vumerity.

B. Biogen Pervasively Marketed Vumerity with the False Claim that It Was Medically Superior to Tecfidera.

330. In the face of imminent entry by generic Tecfidera, Biogen put its switch strategy into high gear. In July 2020 Biogen's CEO announced that

> "since the focus now is on VUMERITY not on the fumarate, I can tell you that all levels [at Biogen] are aligned, at the payer level, at the patient services level, at the salesforce level -- including incentive schemes -- to shape their behavior, at the medical affairs level. So, the organization is absolutely aligned and focused on all of those levers."

331. As one piece of its anticompetitive scheme to switch the market from Tecfidera to Vumerity, Biogen directed its sales force to falsely disparage Tecfidera—and its AB-rated generic substitutes—to doctors, payers, and patients. This disparagement included falsely stating to doctors, payers, and patients that Vumerity had a substantially better GI-tolerability profile than did Tecfidera.

332. Notably, the FDA-approved label for Vumerity does not include any claims of superiority of Vumerity over Tecfidera with respect to side effects or otherwise. Instead, for the reasons described in detail in Section X(B)(2) below, Vumerity is demonstrably *inferior* to Tecfidera.

333. Biogen's promotional efforts in markets outside the United States further confirm that Vumerity is not a clinical improvement over Tecfidera. In those non-U.S. markets, where Tecfidera still has patent protection, Biogen continues to prioritize promoting Tecfidera over Vumerity. For example, in 2022, Biogen's Tecfidera sales outside the U.S. were more than $1 billion, 32 times higher than its Vumerity sales of just $32 million. This stark disparity underscores that Biogen is speaking out of both sides of its mouth: touting Vumerity as an improvement over Tecfidera in the U.S. while sidelining Vumerity abroad.

334. Biogen's relative pricing of the two products further confirms Vumerity's inferiority. At all relevant times, Biogen has set the list price of Vumerity significantly below that of Tecfidera.

335. But in order to switch the U.S. market from Tecfidera to Vumerity, Biogen needed a marketing message that Vumerity was somehow medically superior to Tecfidera. Biogen had obtained FDA approval of Vumerity by proving that it was simply bioequivalent to Tecfidera, just like A/B-rated Tecfidera generics. Without a claim that Vumerity was clinically superior to Tecfidera, the only thing to distinguish them would be price, and the entry of generic Tecfidera would compete the price of fumarate to cents on the dollar compared to Vumerity.

336. So Biogen concocted a claim that Vumerity was clinically superior to Tecfidera in terms of GI-tolerability. That claim was entirely bogus.

337. In some significant ways, Tecfidera is medically superior to Vumerity. Among other things: (a) Tecfidera (and AB-rated Tecfidera generics) require half the number of capsules to be taken by the patient (two capsules per day as compared to four capsules per day for Vumerity); (b) Tecfidera does not pose the same risks as Vumerity to patients with moderate to severe renal impairment; (c) Tecfidera can be taken with a high-fat, high-calorie meal without the

risk of loss of effectiveness that occurs with Vumerity; and (d) for patients who were previously stable on Tecfidera, switching to Vumerity may heighten the risk of a rare white blood cell disorder.

338. Nevertheless, Biogen's false claims that Vumerity was clinically superior to Tecfidera because Vumerity had improved GI-tolerability were highly effective. When a brand-drug manufacturer disparages its own product as part of a market-switch campaign, no other market participant has the practical and economic ability to counter the false marketing.

339. Manufacturers of rival brand drugs had no economic incentive to counter Biogen's false message: successful entry by generic Tecfidera would only lower the average price of fumarate. So only the generic manufacturers, through an expensive marketing campaign, could counter Biogen's false assertions. Such coordination would be beset by free-rider problems—each individual manufacturer's self-interest is to not contribute to the cost, but reap the benefits of the others' contributions. Indeed, one purpose of the AB-rated substitution mechanism is to eliminate costly marketing expenditures by generic companies whose products are in fact undifferentiated. Generic substitution, when it works as intended, focuses competition primarily on price.

1. The FDA Concluded that Vumerity Has "No Meaningful Differences" from Tecfidera as to GI Side Effects.

340. Before entering a License and Collaboration Agreement with Biogen concerning Vumerity (a/k/a ALKS 8700) on November 27, 2017 (the "Biogen-Alkermes Agreement")[3],

[3] Biogen and Alkermes Announce License and Collaboration Agreement to Develop and Commercialize ALKS 8700 for the Treatment of Multiple Sclerosis, *available at* https://investor.alkermes.com/news-releases/news-release-details/biogen-and-alkermes-announce-license-and-collaboration-agreement (last visited Aug. 13, 2025).

Alkermes had begun clinical studies. These clinical studies went by the names EVOLVE-MS-1 and EVOLVE-MS-2.

341. EVOLVE-MS-1, a study begun on December 10, 2015 and sponsored by Biogen, evaluated the safety of Vumerity in patients with MS. *See* https://clinicaltrials.gov/study/NCT02634307 (last visited Aug. 13, 2025). The FDA required the study as a condition of approving the drug.

342. EVOLVE-MS-2, begun on March 15, 2017 and also sponsored by Biogen, was a five-week study purportedly evaluating the gastrointestinal ("GI") tolerability of Vumerity as compared to Tecfidera. *See* https://clinicaltrials.gov/study/NCT03093324 (last visited Aug. 13, 2025). No such study was required for Vumerity to obtain FDA approval.

343. Tecfidera and Vumerity are both known to cause GI side effects in some patients. Vumerity FDA Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211855s000lbl.pdf ("Flushing and GI reactions (abdominal pain, diarrhea, and nausea) are the most common reactions, especially at the initiation of therapy, and may decrease over time.") (last visited Aug. 13, 2025).

344. Clinical studies had shown that any GI side effects from Tecfidera typically arose only for first-time Tecfidera patients and only during the first month of treatment, with a substantial reduction of GI side effects thereafter. Tecfidera FDA Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/204063s031lbl.pdf ("The incidence of GI events was higher early in the course of treatment (primarily in month 1) and usually decreased over time in patients treated with TECFIDERA compared with placebo. Four percent (4%) of patients treated with TECFIDERA and less than 1% of placebo patients discontinued due to gastrointestinal events. The incidence of serious GI events was 1% in clinical trial patients

treated with TECFIDERA; these events, none of which were fatal, included vomiting (0.3%) and abdominal pain (0.3%).") (last visited Aug. 13, 2025). Years of clinical practice with Tecfidera had found that its GI side effects can "usually be managed using several lifestyle or medication changes," including taking Tecfidera with food (especially a high-fat, high-calorie meal or snack) or with aspirin. *See* MS Trust, *What are the best ways to reduce flushing and GI upset when using dimethyl fumarate (Tecfidera)*, *available at* https://mstrust.org.uk/news/research/best-ways-reduce-flushing-and-gastrointestinal-upset-tecfidera (last visited Aug. 13, 2025).

345. In the EVOLVE-MS-2 study, Biogen and Alkermes purported to evaluate the comparative GI tolerability of Vumerity versus Tecfidera using patient-self-administered questionnaires. Alkermes crafted two scales for the study, which it dubbed the IGISIS and the GGISIS (respectively the Individual Gastrointestinal Symptom and Impact Scale, and the Global Gastrointestinal Symptom and Impact Scale) to purportedly reflect the severity of any GI side effects. *See* Clinical Study Report, ALK8700-A302, *available at* https://www.biogentriallink.com/content/dam/global-development/general/biogen-trial-link/educational/en-us/pdf/csr/NCT03093324-Synopsis.pdf (last visited Aug. 13, 2025).

346. EVOLVE-MS-2 used an "adaptive" study design divided into two parts: Part A and Part B. As part of the Biogen-Alkermes Agreement, Biogen had the right to request changes to Part B based on the results from Part A to ensure Part B was designed "to sufficiently differentiate between the Alkermes 8700 Product [Vumerity] and Tecfidera® with respect to GI Events."

347. It was essential to Biogen's market-switch scheme to differentiate Vumerity from Tecfidera as having fewer GI side effects than Tecfidera. Thus, EVOLVE-MS-2 (a/k/a ALKS8700-A302) was central to the scheme. Biogen and Alkermes told investors in announcing the Biogen-Alkermes Agreement that Biogen's "novel, oral, fumarate therapy [Vumerity] [was]

intended to provide a differentiated gastrointestinal tolerability profile"[4] and Alkermes acknowledged that "[a]ctual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties [including] whether the results from the head-to-head study to evaluate the GI tolerability of ALKS 8700 [Vumerity] compared to TECFIDERA will show that ALKS 8700 has more favorable GI tolerability."

348. In. December 2018 Biogen and Alkermes submitted an NDA for Vumerity to the FDA. *See* FDA Vumerity Clinical Review File at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211855Orig1s000MedR.pdf (last visited Aug. 13, 2025). They submitted the Vumerity NDA under the abbreviated 505(b)(2) pathway, which means that they relied on Vumerity's bioequivalence to Tecfidera to gain FDA approval for Vumerity, much like generics to Tecfidera relied on being bioequivalent to Tecfidera to gain FDA approval. Under the 505(b)(2) pathway, EVOLVE-MS-1 was the only clinical study that Biogen and Alkermes were required to submit to obtain FDA approval. They also voluntarily submitted Part A of the EVOLVE-MS-2 study. *Id.* at 67.

349. On July 30, 2019, while the Vumerity NDA was pending with the FDA, and three months before the FDA approved Vumerity, Biogen announced "positive topline results" from Part B of the EVOLVE-MS-2 study, stating that Vumerity "demonstrated significantly improved gastrointestinal tolerability" compared to Tecfidera. *See* Alkermes and Biogen News Release, *Diroximel Fumarate Demonstrated Significantly Improved GI Tolerability Profile Compared to*

[4] Biogen and Alkermes Announce License and Collaboration Agreement to Develop and Commercialize ALKS 8700 for the Treatment of Multiple Sclerosis, *available at* https://investor.alkermes.com/news-releases/news-release-details/biogen-and-alkermes-announce-license-and-collaboration-agreement (last visited Aug. 13, 2025) (capitalization changed).

Dimethyl Fumarate in Patients with MS (July 30, 2019), *available at* https://investors.biogen.com/news-releases/news-release-details/diroximel-fumarate-demonstrated-significantly-improved (last visited Aug. 13, 2025).

350. But Biogen did not submit Part B of EVOLVE-MS-2 to the FDA, even though the FDA's review of the Vumerity NDA including Part A of EVOLVE-MS-2 was then ongoing. Indeed, Biogen **never** submitted Part B of EVOLVE-MS-2 to the FDA.

351. In October 2019, FDA approved Vumerity for marketing. But the agency rejected Biogen's claim that Vumerity had improved GI tolerability compared to Tecfidera. FDA instead found that Vumerity and Tecfidera had "comparable" side effects and that "[t]here do not appear to be any additional benefits with [Vumerity] other than what is claimed for the referenced product, Tecfidera." FDA further noted that the EVOLVE-MS-2 study contributed little to the "substantial evidence" that would be required to make any marketing claim under FDA regulations. *See* FDA Vumerity Clinical Review File at 72, 80 *available at* https://www.accessdata.fda.gov/drugsatfda_docs/ nda/2019/211855Orig1s000MedR.pdf (last visited Aug. 13, 2025).

352. The FDA further commented in its Summary Memorandum for Regulatory Action ("Summary Review") on the Vumerity NDA: "The applicant submitted data reflecting safety findings in patients from the initial phase (Part A) of [EVOLVE-MS-2] . . . there were no meaningful differences between adverse event rates for the two treatments[.]." *See* FDA Summary Memorandum at Table 5, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/ nda/2019/211855Orig1s000SumR.pdf. The FDA further noted, taking into account data from EVOLVE-MS-1 in addition to EVOLVE-MS-2 Part A, that: "In a comprehensive review of the adverse events by trial . . . the most common adverse events [with Vumerity] other than flushing

were from the gastrointestinal disorders system organ class, and the pattern of treatment-associated mild adverse events overall was consistent with what is expected with Tecfidera." *Id.* at § 8.

353. In short, the FDA concluded that Vumerity was not superior to Tecfidera and contradicted Biogen's claim that Vumerity had improved GI tolerability over Tecfidera based on both EVOLVE-MS-1 and Part A of the EVOLVE-MS-2 study.

354. Indeed, EVOLVE-MS-2 instructed patients to avoid taking the study drug (either Tecfidera or Vumerity) with a high-fat, high-calorie meal. *See* Clinical Study Protocol at 4, *available at* https://cdn.clinicaltrials.gov/large-docs/24/NCT03093324/Prot_000.pdf (last visited Aug. 13, 2025). This is because when a patient takes Vumerity with a high-fat, high-calorie meal, Vumerity may be less effective. *See* FDA Vumerity Clinical Pharmacology and Biopharmaceutics Review File, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211855Orig1s000ClinPharmR.pdf ("Diroximel fumarate 462 mg [Vumerity] met the bioequivalence (BE) criteria for both AUC and Cmax parameters of MMF relative to DMF 240 mg [Tecfidera], under fasted conditions. DRF [Vumerity] administered with a high-fat/high/calorie meal met the criteria for BE to DMF based on AUC for MMF, however mean Cmax for MMF was 26% lower compared to that of DMF administered under the same (high fat) conditions, which is out of BE criteria.") (last visited Aug. 13, 2025). Biogen withdrew its Vumerity approval application in Canada because the Canadian regulators had raised issues with Vumerity's bioequivalence to Tecfidera when taken with a high-fat, high-calorie meal or snack. *See* Health Canada, Summary of Cancellation for diroximel fumarate (*Vumerity), *available at* https://dhpp.hpfb-dgpsa.ca/review-documents/resource/RDS1692973508042 (last visited Aug. 13, 2025).

355. The FDA also noted this issue, but took a different path. Vumerity's FDA-approved label advises that patients should not take Vumerity with a high-fat, high-calorie meal or snack. This language does not appear on the Tecfidera label. Past practice with Tecfidera advised patients to take Tecfidera *with* a high-fat, high-calorie meal or snack to avoid GI side effects, especially during the first month of treatment.

356. Thus, the instruction in EVOLVE-MS-2 to avoid taking study drugs (either Tecfidera or Vumerity) with a high-fat, high-calorie meal tended to skew the study results toward finding less GI side effects with Vumerity relative to Tecfidera because Tecfidera is optimal with such a meal and Vumerity is optimal without such a meal. Notably, even with the inherent bias in the study's design (withholding the optimal conditions for Tecfidera's GI tolerability from patients by disallowing such a meal), the FDA concluded that the study nevertheless failed to show that Vumerity was superior to Tecfidera with respect to GI tolerability.

357. The FDA nonetheless approved Vumerity for marketing because the governing statute and regulations did not require that it be superior in any way in order to gain approval. All that was required was that it be safe and bioequivalent to Tecfidera, just like Tecfidera generics.

2. Other Global Regulators Concur with the FDA that Vumerity Does Not Have Any GI Benefit Over Tecfidera Based on Both Parts A and B EVOLVE-MS-2.

346. Biogen also failed to convince other global regulators that the EVOLVE-MS-2 study supported Biogen's claim that Vumerity had improved GI tolerability. The FDA's European Union counterpart, the European Medicines Agency ("EMA"), French counterpart, the Haute Autorité de Santé ("HAS"), and Australian counterpart, the Pharmaceutical Benefits Advisory Committee ("PBAC"), each rejected Biogen's claim of improved GI tolerability for Vumerity, even after considering the EVOLVE-MS-2 Part B results—that were never submitted to FDA—

that Biogen relied on in the U.S. as demonstrating Vumerity's "significantly improved gastrointestinal tolerability" as compared to Tecfidera.

European Medicines Agency ("EMA")

347. On November 16, 2020, Biogen applied for marketing approval to the EMA. *See* European Medicines Agency, Vumerity Assessment Report at 82 (Sept. 16, 2021) (under "Assessment history," "Initial marketing authorisation documents, titled "Vumerity : EPAR – Public assessment report) (last visited Aug. 13, 2025). To support its application, Biogen submitted results from both Parts A and B of the EVOLVE-MS-2 study.

348. The EMA rejected Biogen's assertion that the EVOLVE-MS-2 study supported Biogen's superior GI tolerability claims, concluding that "the results of the study [EVOLVE-MS-2] cannot be considered adequate to allow inclusion of a claim in the [summary of product characteristics] of [Vumerity], due to a number of deficiencies such as: validity of scales, choice of Number of Days with any IGISIS Symptom Intensity Score ≥ 2 relative to exposure days as an endpoint, robustness of statistical analyses and the lack of clinically relevant and meaningful findings[.]" *Id*. at 134.

349. The EMA found that Biogen had not shown EVOLVE-MS-2 to provide clinically meaningful results to justify Biogen's increased GI tolerability claim:

- "[I]t could not be robustly demonstrated that [the primary] endpoint was an appropriate one to provide a clinically relevant and meaningful outcome. The number of event days are very small. Even with an IGISIS symptom intensity score ≥ 2 the difference between the [Vumerity] and the [Tecfidera] group was less than 1 day." *Id*. at 135.

- "It is still unclear what difference in the scales used in the Study A302 constitutes a minimal significant clinical difference (the primary endpoint was pre-defined as the number of days IGISIS individual symptom intensity score ≥ 2)." *Id*. at 87.
- "[T]he informative value of the study claiming favourable GI tolerability has found to be low and the clinical relevance of numerical differences in GI tolerability between DRF and DMF could not be deduced from the provided data." *Id*. at 118.
- "[B]etween the [Tecfidera] and the [Vumerity] group, the differences in the percentages for specific GI [adverse events] . . . were very small and their clinical significance to justify an advantage of [Vumerity] vs [Tecfidera] is questionable." *Id*. at 89.
- "[I]t is still unclear what difference between the assessed therapies constitutes a minimally significant or a clinically meaningful difference for IGISIS and GGISIS." *Id*. at 83.
- "Such small differences between the two groups, using scales of questionable validity and specificity, with results from both parts A and B and from a single Study [EVOLVE-MS-2], cannot be considered as an appropriate justification able to support an advantage in GI tolerability for [Vumerity]." *Id*. at 134

350. The EMA also noted "several issues" with the IGISIS and GGISIS scales utilized in the EVOLVE-MS-2 study. *Id*. First, the scales were patient-reported, for which "[b]ias could be an inherent characteristic." *Id*. Second, the clinical usefulness of the scales was unclear: "when the number of days with any IGISIS score ≥ 4, ≥ 5, ≥ 6 were evaluated the numbers were below unit 1 in both groups ALKS-8700 (DRF) and DMF showing that the numbers are very low to draw

any clinically meaningful conclusions and questioning the clinical usefulness of these scales." *See id.* at 50; *see also id.* at 88 ("It is noted that the Number of Days with any IGISIS Symptom Intensity Score ≥ 3 is below 1 for ALKS 8700 (DRF) (0.9) for Part A and B combined and Part B only (0.7). These numbers are very low to draw any clinically meaningful conclusions and are questioning the clinical usefulness of these scales."). Third, the scales were not validated and "[i]t is questionable whether the findings from these scales would be reproducible and consistent with another treatment for MS" including because "[b]ias, increased patients' expectations and tailored modified scales (similar to a 'cherry picking' approach) may have been introduced in the measurements." *See id.* at 135. Fourth, the IGISIS scale was designed in a way that "may not be a true reflection of the clinical condition of the patient" because it did not represent the worsening or improvement of a symptom. *Id.* at 144.

351. The EMA further questioned the relevance of the choice of primary endpoint (the very endpoint that was lowered from ≥3 on the IGISIS 11-point scale in Part A to ≥2 in Part B), noting that "[t]he clinical relevance of the choice of the endpoint is still not established. One could argue that a result—driven approach was applied for the choice of intensity score ≥ 2." *See id.* at 88 (emphasis added).

352. The EMA also criticized the study's analysis of the data. In particular, the EMA pointed to "improper handling of missing evaluable diaries." *Id.* at 136. Patients used an e-diary to record symptoms. The diary was considered "evaluable" when "a subject took [the] study drug prior to completing the diary and completed the diary within the recommended reporting window. *Id.* at 43. The EMA noted, "[f]or a considerable number of days the diaries were not evaluable or valid, which may also include completely missing diaries." *Id.* at 136. The EMA requested additional justification for Biogen's treatment of the non-evaluable diaries, and after considering

Biogen's arguments, emphasized that "the robustness of the analysis regarding the large amount of non-evaluable diaries still remains unclear." *Id.* at 45 (emphasis in original).

353. In summary, on review of both Parts A and B of the EVOLVE-MS-2 study, the EMA concluded that "no significant difference on GI tolerability with DRF [Vumerity] over DMF [Tecfidera] can be claimed." *Id.* at 97.

Haute Autorité de Santé ("HAS")

354. France's HAS concluded its review of Vumerity on February 16, 2022, considering both Part A and Part B of the EVOLVE-MS-2 study, and rated Vumerity as L'amélioration du Service Médical Rendu (ASMR) level V, which indicates that Vumerity does not provide an improvement compared to Tecfidera. *See* Diroximel Fumarate Première évaluation at §§ 5.1.2.2, 07.2 https://www.has-sante.fr/upload/docs/evamed/CT-19534_VUMERITY_PIS_INS_AVIS%20DEF_CT19534.pdf (last visited Aug. 13, 2025); *see also* https://www.has-sante.fr/jcms/r_1506267/fr/le-service-medical-rendu-smr-et-l-amelioration-du-service-medical-rendu-asmr (last visited Aug. 13, 2025).

Australia's Pharmaceutical Benefits Advisory Committee

355. A report by Australia's Pharmaceutical Benefits Advisory Committee ("PBAC"), which evaluates the clinical effectiveness of drugs and makes recommendations regarding their use and reimbursement, came to similar conclusions as the FDA, EMA, and HAS.

356. The PBAC noted concerns about Biogen's deviations from the EVOLVE-MS-2 study protocols. Biogen conducted an unblinded analysis of EVOLVE-MS-2 Part A data to inform changes to the study endpoints for Part B, (ALK8700-A302 Statistical Analysis Plan at 7, https://cdn.clinicaltrials.gov/large-docs/24/NCT03093324/SAP_001.pdf ("Following completion of Part A, the sponsor conducted a planned, unblinded analysis of the Part A GI tolerability and

safety data.") (last visited Aug. 13, 2025)) disregarding the importance of blinded interim analysis to avoid bias. *See* Laura E. Bothwell et al, *Adaptive design clinical trials: a review of the literature and ClinicalTrials.gov* (Feb. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5829673/#SP1 ("Statisticians and regulatory experts have strongly recommended establishing safeguards to maintain interim analysis blinding from investigators, sponsors or anyone outside [independent data monitoring committees] to avoid introducing bias into ensuing study design, conduct, or interpretation.") (last visited Aug. 13, 2025). The PBAC report "noted that while the EVOLVE-MS-2 trial met its primary endpoints, the deviation from protocol potentially introduced bias and confounding to the study, thus adversely impacting the generalisability of the study results. The protocol amendments included changes in primary, secondary and exploratory endpoints, and sample size to maintain study power, and choice of a pooled analysis in the primary endpoint." *See* Public Summary Document – March 2022 PBAC Meeting at 9, *available at* https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-03/files/diroximel-fumarate-psd-march-2022.pdf (last visited Aug. 13, 2025).

357. The PBAC, like other regulators, also noted concerns Biogen's bespoke measurement scales—the IGISIS and GGISIS—"were exploratory measurement tools and have not been validated or used in previous clinical trials." *Id.* at 12. The PBAC further noted: "The submission also claimed that DRF [Vumerity] has an improved overall safety profile compared to DMF [Tecfidera], particularly with respect to GI tolerability. The claim might not be well supported due to the potential bias in the EVOLVE-MS-2 trial." *Id.* at 14.

358. The PBAC ultimately concluded only that Vumerity was merely "non-inferior" in terms of GI tolerability compared to Tecfidera. *Id.* at 1.

Biogen's Own Admissions

359. Biogen later admitted, albeit only in the "fine print," that it lacked any substantial evidence or substantial clinical experience to support a claim that Vumerity had better GI tolerability than Tecfidera. More than a year after Vumerity launched (and after generic Tecfidera launched), Biogen admitted the EVOLVE-MS-2 results had to be "interpreted with caution due to the 5-week duration," "the data may not be [] reliable," "additional studies may be needed to confirm" the findings from EVOLVE-MS-2, "it can be hard to compare stomach problems," the IGISIS and GGISIS scales were not validated, and "the mean number and percent of days with maximum symptom scores >0 for either GI tolerability instrument were low, which complicates the interpretation of the data derived from these instruments [IGISIS and GGISIS]." Biogen made even these fine-print admissions only on its doctor and patient websites, omitting them when it vigorously peddled its false claims of Vumerity superiority—without any of these admissions—to doctors, payers, patients, and other industry participants.

3. Biogen Relentlessly Promoted Its Misrepresentations to Doctors, Payers and Patients.

360. Biogen well knew that the FDA standard for whether drug marketing statements are "false, lacking in fair balance, or otherwise misleading" is whether the manufacturer has substantial evidence or substantial clinical experience to support the marketing statements. *See* 21 C.F.R. §§ 202.1(e)(6)(i), (ii), (iv), (v) & 21 C.F.R. §§ 202.1(e)(7)(i), (ii), (iii). But even after the FDA had concluded that EVOLVE-MS-2 failed to provide such "substantial evidence" and had rejected the claim that Vumerity had better GI tolerability compared to Tecfidera, Biogen continued to make this claim before, during, and after it began marketing Vumerity. This was also despite the fact that numerous government regulators reached the same conclusions as FDA.

361. Biogen engaged in a pervasive marketing campaign to MS doctors, payers, and patients, a cornerstone of which was the false assertion that Vumerity had better GI tolerability than Vumerity. These are a small sample of Biogen's false marketing statements:

- "Diroximel fumarate [Vumerity] demonstrated statistically superior GI tolerability compared to dimethyl fumarate [Tecfidera]." *See* Alkermes and Biogen News Release, *Diroximel Fumarate Demonstrated Significantly Improved GI Tolerability Profile Compared to Dimethyl Fumarate in Patients with MS* (July 30, 2019), *available at* https://investors.biogen.com/news-releases/news-release-details/diroximel-fumarate-demonstrated-significantly-improved.

- "Vumerity was generally safe and well-tolerated, with patients having fewer gastrointestinal reactions." *See* Patricia Inacio, *Vumerity Approved in US as Treatment for RRMS and Active SPMS*, MS News Today [note this is paid marketing] (Oct. 30, 2019), *available at* https://multiplesclerosisnewstoday.com/news-posts/2019/10/30/biogen-and-alkermes-announce-fda-approval-of-vumerity-diroximel-fumarate-for-multiple-sclerosis/.

- "VUMERITY was associated with significantly shorter duration, severity and daily impact of five key GI symptoms, compared to TECFIDERA." Biogen News Release, *Biogen Presents Data Demonstrating Improved GI Tolerability with Vumerity Compared to Tecfidera* (Nov. 22, 2019), *available at* https://investors.biogen.com/news-releases/news-release-details/biogen-presents-data-demonstrating-improved-gastrointestinal.

- "VUMERITY was statistically superior to TECFIDERA." *See* Biogen 2019 10-K filed on Feb. 6, 2020.
- "Findings from the five-week EVOLVE-MS-2 study reinforce clinically meaningful improvements in patient-assessed gastrointestinal (GI) tolerability associated with VUMERITY treatment compared to TECFIDERA, and supports its impact on quality of life for people with relapsing MS." *See* Biogen News Release, *New Data at ACTRIMS-ECTRIMS Meeting Showcase Safety and Efficacy of Biogen's Industry-Leading MS Portfolio* (Sept. 11, 2020), *available at* https://investors.biogen.com/news-releases/news-release-details/new-data-actrims-ectrims-meeting-showcase-safety-and-efficacy.

362. Biogen's sales force systematically delivered these false claims of Vumerity's GI superiority compared to Tecfidera to doctors, payers, and patients throughout the nation. And Biogen made the sales persons' remuneration depend on how many doctors they switched from writing prescriptions for Tecfidera to writing them for Vumerity.

363. Biogen also paid many millions of dollars to MS physicians to promote Vumerity on the false basis that it had significantly improved GI tolerability compared to Tecfidera. Biogen knew that most fumarate prescriptions are controlled by a concentrated group of MS physicians who have significant influence over their patients' prescription purchases. *See* Relators' Third Amended Complaint, ECF 132 at ¶ 52, *United States of America, et al., ex rel. Michael Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601 (D. Mass.), *available at* https://www.statnews.com/wp-content/uploads/2022/07/THIRD-AMENDED-COMPLAINT-biogen-bawduniak.pdf (last visited Aug. 13, 2025).

364. Biogen has a history of making false promotions and has paid enormous sums of money to settle allegations that it made illegal kickbacks to MS physicians to encourage use of its drugs, including Tecfidera. *See Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments* (Sept. 26, 2022), *available at* https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments (last visited Aug. 13, 2025). In September 2022, Biogen agreed to pay $900 million to resolve allegations that it caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce them to prescribe Biogen drugs, including leading up to and during the launch of Tecfidera in 2013. *See Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments* (Sept. 26, 2022), *available at* https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments (last visited Aug. 13, 2025). Biogen has also previously been sanctioned by the FDA for false promotions relating to its other MS drugs, including Avonex and Tysabri. *FDA Cites Biogen Idec for Misleading Web Promotions of MS Drug Avonex*, Bloomberg Law (Mar. 23, 2012), *available at* https://news.bloomberglaw.com/pharma-and-life-sciences/fda-cites-biogen-idec-for-misleading-web-promotions-of-ms-drug-avonex (last visited Aug. 13, 2025); Ltr. from FDA to Biogen Idec dated Mar. 25, 2010 Concerning Tysabri, *available at* https://www.fdanews.com/ext/resources/ files/archives/t/TysabriLetter.pdf (last visited Aug. 13, 2025). Alkermes, too, has a recent history of including false or misleading information in its promotional advertising in connection with its drug products. *See, e.g.*, *FDA Warning Letter to Alkermes, Inc. re. NDA 021897 VIVITROL (naltrexone for extended-release injectable suspension)* (December 2, 2019) (warning Alkermes that its print advertisement is "false or misleading because it omits important risk information associated with the use of Vivitrol"),

available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/alkermes-inc-597260-12022019 (last visited Aug. 13, 2025).

365. Despite Biogen's substantial payments to the government to resolve allegations of false promotion and illegal kickbacks to MS physicians, Biogen's payments to MS physicians to induce use of Biogen's MS drugs never stopped. Between 2019 and 2022 alone, Biogen made approximately $70 million worth of "general payments" to physicians, including millions of dollars for food and beverage, travel, and miscellaneous consulting. *See* openpaymentsdata.cms.gov (last visited Aug. 13, 2025). Many such payments were to induce MS physicians to prescribe Biogen's branded products including Vumerity.

366. For just one example, between 2019 and 2022 a particular physician received approximately $350,000 in payments from Biogen, and he received over a million dollars in payments from Biogen over the course of his career.

367. When FDA approved Vumerity, the Multiple Sclerosis Association of America ("MSAA") put out a statement that was "reviewed" by this particular doctor concerning the launch. The statement also included a quote from the doctor, which stated in pertinent part: "Vumerity is a new therapeutic option for people with MS. While its efficacy is comparable to Tecfidera, this newly approved medication has a lower incidence of gastrointestinal side effects . . . we welcome these new agents that provide new and valuable treatment options for the MS community." *See* MSAA, Vumerity Oral Capsules Approved by the FDA (Oct. 31, 2019), *available at* https://mymsaa.org/news/vumerity-approved-fda-adults-relapsing-ms-including-spms/ (last visited Aug. 13, 2025). The doctor's statement contained no disclaimer noting that he had received hundreds of thousands of dollar from Biogen and, contrary to his statement, the FDA had, prior to his statement, concluded that "[t]he frequency and nature of [side effects with Vumerity] . . .

appears. . . similar to what would be expected with the referenced product, Tecfidera." *See* FDA Vumerity Clinical Review File, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211855Orig1s000MedR.pdf (last visited Aug. 13, 2025). Thus, the statement that Vumerity had a "lower incidence of gastrointestinal side effects" was patently misleading and, at best, unproven.

368. The MS physician community is tightly-knit, and that doctor's false promotion on behalf of the MSAA was well-publicized and would have been known to many, if not most, fumarate prescribers, influencing them to prescribe Vumerity over Tecfidera.

369. Biogen's anticompetitive switch conduct included its messaging to insureds. Beginning in late 2020, patients' attempts to visit the Tecfidera webpage were automatically intercepted by a different webpage informing them of another option–Vumerity. From that page, patients could either choose to visit the Vumerity webpage or continue to the Tecfidera site.

https://www.tecfidera.com (last visited Aug. 13, 2025).

370. Biogen made the same false statements directly to patients, including through Biogen's paid spokespersons, that it had made to doctors:

- "While [Vumerity]'s efficacy is comparable to Tecfidera, this newly approved medication has a lower incidence of gastrointestinal side effects." *See* MSAA, *Vumerity Oral Capsules Approved by the FDA*, MSAA (Oct. 31, 2019), *available at* https://mymsaa.org/news/vumerity-approved-fda-adults-relapsing-ms-including-spms/ (last visited Aug. 13, 2025).
- "Vumerity is different and has less gastrointestinal problems. . . . Gastrointestinal issues are common but not to the extent with Tecfidera." *See New MS Drug Provides Relief, Fewer Side Effects*, Healthline (Nov. 14, 2019), *available at* https://www.healthline.com/health-news/new-ms-drug-provides-relief-fewer-side-effects (last visited Aug. 13, 2025).

- "Vumerity was better tolerated and had significantly fewer reported gastrointestinal symptoms compared to Tecfidera." *See* Living with MS (Oct. 2020), *available at* www.saundersmedicalcenter.com (last visited Aug. 13, 2025).
- "When i talked to the guy at Biogen originally before switching he told me that the Vumerity and Tecfidera are chemically similar but the effects on the body are way less with Vumerity." *See* Vumerity in place of Tecfidera (Apr. 28, 2021), *available at* https://www.reddit.com/r/MultipleSclerosis/comments/n0fm3j/comment/gw6qqtf (last visited Aug. 13, 2025).

371. Biogen also made the same false statements to PBM formulary committees and to state Medicaid committees. For example, at the Alaska Medicaid P&T Committee Meeting on November 20, 2020, "LYNDA FINCH, a representative of Biogen, discussed Vumerity (Diroximel Fumarate). It was approved by the FDA on October 30, 2019, for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting MS, and active secondary progressive MS in adults. Its distinct chemical structure was reviewed. Due to its bioequivalence to Tecfidera, we can expect to see the same efficacy and safety profile as Tecfidera. It also carries the same warnings and precautions on its label. However, Vumerity has demonstrated an improved GI tolerability profile compared to Tecfidera in a study published in January 2020. Several studies and their outcomes were reviewed. While Tecfidera had only a 4% discontinuation rate in clinical studies, we see rates of 20% in the real-world settings. While GI events resolve in the first month or two for most patients, there are patients who suffer prolonged GI intolerability. This is a progressive illness, and it is important to have access to medications that are both efficacious and tolerable to maintain adherence and prevent relapses in disability

progression. We request that you consider adding Vumerity to the [formulary] as an option for your patients with relapsing forms of MS." *See* Alaska Medicaid P&T Committee Meeting Minutes, https://health.alaska.gov/dhcs/Documents/pdl/PNT-Meeting-Minutes/PNT_Minutes_20201120.pdf (last visited Aug. 13, 2025).

372. The notes of the OptumRx Silver State Scripts Board Meeting of January 21, 2021 are to the same effect: "Comment was by Kaysen Bala with Biogen speaking on behalf of Vumerity. Described the similarities to Tecfidera in efficacy and indication, but with better GI tolerability. Offered some new information on clinical study information, GI tolerability was better in Vumerity compared to Tecfidera resulting in better quality of life score and better long-term adherence. Requested the committee add Vumerity as preferred." *See* OptumRx Silver State Scripts Board Draft Meeting Minutes (Sept. 24, 2020), https://dhcfp.nv.gov/uploadedFiles/dhcfpnvgov/content/Public/AdminSupport/MeetingArchive/SSSB/2020/SSSB_09_24_20_Minutes_Final.pdf (last visited Aug. 13, 2025).

373. At the Washington State Health Care Authority Meeting on October 20, 2021, Biogen's Linda Finch again repeated the false assertions: "The evolve MS two study is a phase three randomized, active controlled head to head study that evaluated patient reported GI tolerability for humanity versus Tecfidera in relapsing MS patients. Patients treated with Vumerity experience a statistically significant improvement in a patient reported outcome measuring GI adverse event symptom intensity." *See* Washington State Health Care Authority Meeting (Oct. 20, 2021), https://www.hca.wa.gov/assets/program/pt-dur-transcript-2021-10-20.pdf (last visited Aug. 13, 2025).

374. Biogen falsely promoted Vumerity and disparaged Tecfidera contemporaneously with the launch of Vumerity and the switching of the market from Tecfidera to Vumerity. The

false claim that Vumerity had the better GI tolerability was the only claim upon which Biogen based its extensive Vumerity marketing campaign; Biogen had nothing else to try to differentiate Vumerity from Tecfidera.

375. The FDA had considered only Part A of the EVOLVE-MS-2 study in rejecting Biogen's improved GI tolerability claim. So the only conceivable basis that Biogen had to support its superiority claims was Part B of the EVOLVE-MS-2, study, which Biogen chose to never submit to the FDA, and which, in any event, multiple international government regulators concluded did not support an improved GI tolerability claim.

376. Nothing about EVOLVE-MS-2 Part B would have led FDA to a different conclusion. EVOLVE-MS-2 Part A and Part B were "identical in study design." *See* Clinical Study Protocol at 3 ("Both Parts A and B are identical in study design and include a 5-week, double-blind treatment period with two blinded treatment arms (ALKS 8700 [Vumerity] and DMF [Tecfidera]). Part A is exploratory and Part B is confirmatory."), https://cdn.clinicaltrials.gov/large-docs/24/NCT03093324/Prot_000.pdf (last visited Aug. 13, 2025); ALK8700-A302 Statistical Analysis Plan at 6, https://cdn.clinicaltrials.gov/large-docs/24/NCT03093324/SAP_001.pdf (last visited Aug. 13, 2025).

377. The only differences between Part A and Part B are that, following discussions between Alkermes and Biogen concerning Part A, data from Part A informed changes to the endpoints (Biogen lowered the primary endpoint from ≥3 to ≥2 on the IGISIS 11-point scale), the statistical analysis methods, and the number of participants in Part B of the study. *Compare* Clinical Study Protocol at 5 ("Primary Endpoint: The number of days with any IGISIS individual symptom intensity score ≥3 relative to exposure days in Part B.") *with* https://clinicaltrials.gov/study/NCT03093324?a=4&tab=results ("Outcome Measures 1. Number

of Days With Any … IGISIS[] Individual Symptom Intensity Score ≥2 Relative to Exposure Days in Parts A and B"). Such differences would not have changed the conclusions that the FDA reached based on EVOLVE-MS-2 Part A. The results and data from Part B were like the results and data from Part A, except with a bigger sample size. Thus, EVOLVE-MS-2 Part B could not be "substantial evidence" for the claim that Vumerity has a significantly improved GI side effect profile compared to Tecfidera.

378. Such "small differences between the two groups . . . using scales of questionable validity and specificity, with results from both parts A and B and from a single Study [EVOLVE-MS-2] cannot be considered as an appropriate justification able to support an advantage in GI tolerability for [Vumerity]." *See* European Medicines Agency, Vumerity Assessment Report at 93 (Sept. 16, 2021) (last visited Aug. 13, 2025).

379. Despite understanding the FDA standard for drug comparative marketing claims and Biogen's own statements that "[a]dditional studies may be needed to confirm these findings [of EVOLVE-MS-2 Part B]," (https://www.vumerity.com/en_us/home/about/common-side-effects.html (last visited Aug. 13, 2025)). Biogen never conducted any other studies to support its improved GI tolerability claims. Nor did Biogen ever take actions to file with the FDA for a label change as Biogen had indicated would happen if Vumerity's improved GI tolerability claims were "clear and compelling" such that Vumerity had "true differentiation" from Tecfidera. *See* Alkermes Earnings Call (Apr. 27, 2017) at 12; Alkermes Earnings Call (July 27, 2017) at 11; Bernstein Strategic Decisions Conference (May 30, 2019) at 12 (Biogen indicating that if the clinical data supporting the improved GI tolerability claim for Vumerity looked good then it may seek a label change).

380. In short, knowing that it lacked substantial evidence or substantial clinical experience, and having been rejected by the FDA and other regulators, Biogen nevertheless pressed forward falsely disparaging Tecfidera and promoting Vumerity to physicians, patients, and payers claiming that Vumerity offered a "significantly improved GI tolerability profile compared to dimethyl fumarate [generic Tecfidera]" and providing no disclaimers about the faulty, FDA-criticized EVOLVE-MS-2 study that was the sole basis on which such a claim could be based. *See* Biogen News Release, *Diroximel Fumarate Demonstrated Significantly Improved Gastrointestinal Tolerability Profile Compared to Dimethyl Fumarate in Patients with MS* (July 30, 2019), *available at* https://investors.biogen.com/news-releases/news-release-details/diroximel-fumarate-demonstrated-significantly-improved. Biogen's anticompetitive intent was to destroy the prescription base for Tecfidera and move them to Vumerity.

381. Biogen further exacerbated its false and misleading GI tolerability claims by not disclosing the extensive limitations and disclosures Biogen was aware of when it was disparaging Tecfidera and unlawfully promoting Vumerity to patients and others in advance of, during, and after generic Tecfidera launch, between at least as early as July 2019 and continuing to the present. Moreover, Biogen's improved GI tolerability claims misleadingly implied that Vumerity was a superior choice for *all* patients with relapsing MS. In reality, even if Vumerity had actually demonstrated improved GI tolerance, it would be a superior choice for only new fumarate patients and those encountering ongoing GI side effects from Tecfidera (which has been shown to be a small portion of patients in clinical studies).

382. GI side effects typically occur for patients in their first month starting out on Tecfidera or Vumerity as their first fumarate treatment. Biogen's claims did not disclose that patients who were already stable on Tecfidera could be *more likely* to experience GI side effects

by switching to Vumerity, especially in the first month after they were switched. This is because patients who were already stable on Tecfidera would have gotten through their first month of treatment when GI side effects are known to occur. By switching such patients who were already stable on Tecfidera without GI side effects to Vumerity, it only placed such patients at risk of a new round of GI side effects in their first month on Vumerity.

383. And even if Biogen had made the disclosures discussed above, that would not have made the promotion compliant with FDA regulations; Biogen lacked substantial evidence or substantial clinical experience, and the claims were therefore false and misleading under FDA regulations, disparaged Tecfidera without any basis, and should not have been made at all.

C. Biogen Obscured Price Signals as Between Vumerity and Generic Tecfidera.

384. As it had done with respect to Tecfidera and generic Tecfidera, Biogen obscured the price signals that insureds received as between the costs of Vumerity and generic Tecfidera. In fact, generic Tecfidera was available at a small fraction of the price of Vumerity—at discounts approaching 90%.

385. But Biogen eliminated the price signals that would have provided accurate price information for doctors and insureds to consider in weighing the decision as to which product to buy. Biogen paid the Co-Conspirator PBMs to place generic Tecfidera on the same formulary tier as Vumerity, and it provided patient coupons that eliminated the copayment or coinsurance obligation when the insured selected Vumerity.

1. Biogen Paid the PBMs to Place Generic Tecfidera on the Same Tier as Vumerity.

386. As explained in detail above (Section XIII(A)), Biogen paid the Co-Conspirator PBMs to place generic Tecfidera on the same formulary tier as Tecfidera. That conduct was

anticompetitive because, among other effects, it obscured the true relative costs of Tecfidera and the generics. Biogen ensured that doctors and patients would perceive, wholly inaccurately, that the price of Tecfidera and the generics was the same.

387. Biogen used the same ruse to obscure the true price difference between Vumerity and generic Tecfidera. Biogen paid the Co-Conspirator PBMs to place generic Tecfidera on the same formulary tier as Vumerity.

388. Biogen paid enhanced rebates and fees to Co-Conspirator PBMs in exchange for placing generic Tecfidera on the same or worse tier as Vumerity on the formulary. The payments obscured the price signals received by 28% of insureds.

389. This chart lists the PBM, the year, and the percent of insureds on the PBM's formularies that placed the dramatically lower-cost generic Tecfidera on the same or worse tier than branded Vumerity:

PBM	2021	2022	2023	2024
CVS Caremark	26%	32%	37%	28%
Express Scripts	34%	12%	14%	20%
OptumRx	18%	18%	13%	8%
Humana	67%	32%	62%	27%
MedImpact	22%	19%	14%	20%
All Five PBMs	28%	23%	24%	19%

390. Every one of these affected buyers of fumarate received a false price signal as to the relative costs of Vumerity and generic Tecfidera. As noted in detail above (Section VIII), the anticompetitive effects of obscuring these price signals are obvious and substantial.

391. Biogen also paid enhanced rebates and fees to Co-Conspirator PBMs in exchange for their agreement to impose "utilization management" techniques against generic Tecfidera. The purpose and effect of those techniques was to substantially impair the sale of generic Tecfidera even when it was otherwise nominally on a favorable formulary tier.

392. In Section VIII(C)(2) above, Biogen paid the Co-Conspirator PBMs to either place generic Tecfidera on a tier other than Tier 1 or to impose step edits or prior authorizations on generic Tecfidera on formularies covering about 68% of insureds. Those restrictions, too, impaired the competition between generic Tecfidera and Vumerity. As noted, Biogen paid for a *substantial majority* of insureds to be subjected to the generic being placed on a Tier other than Tier 1 or one or both of a step edit or prior authorization. From 2021 to 2024 the percentage of insureds who were subjected to those restraints were 68%, 71%, 64%, and 61%, respectively.

393. Designating generic Tecfidera as a specialty drug also impaired the competition between Vumerity and generic Tecfidera. In total, well more than 70% of insureds were affected by one or more of the improper tier placement, specialty-pharmacy designation, or utilization-management aspects of Biogen's impairing competition between generic Tecfidera and Vumerity.

2. Biogen Used Patient Coupons to Make Generic Tecfidera Appear More Expensive than Vumerity.

394. As described in detail above (Section IX(A)), patient coupons obscure the price signals that PBMs otherwise can use to ensure that patients appropriately take price into consideration when selecting which drug to buy. Biogen used patient coupons to hide from patients the relative costs of Tecfidera and generic Tecfidera.

395. Biogen used the same anticompetitive tactic with respect to the relative prices of Vumerity and generic Tecfidera. Biogen made patient coupons available for buyers of Vumerity, without regard to financial ability to pay or other economic criteria. Biogen made it falsely appear that Vumerity, for which the patient paid $0, was less costly than generic Tecfidera, for which the patient would pay a copayment or coinsurance. This is despite the fact that in reality the retail cost of Vumerity in 2021 was $7,271, while generic Tecfidera was only $782.21.

396. As noted in detail above (Section X(C)(2)), it is likely that about 33% of insureds used coupons for their Vumerity purchases.

D. Biogen Tied Rebates and Fees on Tecfidera to Formulary Placement of Vumerity.

397. Biogen paid the Co-Conspirator PBMs rebates and fees *on Tecfidera purchases* in exchange for moving Vumerity to a better position on the formulary. The tactic was very effective. When the generics entered the market, Tecfidera had a sales base of $2.6 billion, while Vumerity had sales of only $59.6 million. So a PBM's getting rebates and fees on Tecfidera sales was far more remunerative than getting them on Vumerity.

398. Biogen's linking of Tecfidera rebates and fees to Vumerity formulary placement proved to be a highly effective (though intensely anticompetitive) tactic. For example, before Biogen began using the ploy in May 2020, Vumerity was on the "preferred" brand tier in formularies covering only 1% of insureds. As a result of Biogen's anticompetitive tactic, that percentage skyrocketed to 10% in June 2020 and to 26% by August 2020.

E. Biogen Directly Reduced the Supply of Generic Tecfidera.

399. Biogen directly intervened in the sales of generic Tecfidera, preventing generic sales that would have occurred in a competitive market.

400. An authorized generic ("AG") is a prescription drug made by a brand-drug manufacturer but marketed under a generic label. AGs typically compete, like other generics, at much lower prices than the brand product. With sales of the magnitude of Tecfidera, a competitive market—one unimpaired by the brand manufacturer's anticompetitive conduct—almost always features the brand manufacturer's sale, either directly by itself or through a third party, of an AG.

401. Teva is a pharmaceutical company that markets both brand and generic drugs. On the brand side, Teva is a leader in the MS space, marketing branded and generic MS treatments.

402. Teva was among the many generics that sought to market a generic of Tecfidera. Teva sought to market its own generic Tecfidera product under ANDA No. 210290.

403. On or about August 25, 2020, however, Biogen and Teva entered into an agreement for Teva to market an AG of Tecfidera rather than launching its own generic Tecfidera under its own ANDA. Under this agreement, Biogen agreed to sell Tecfidera to Teva, which Teva would then market as the AG of Tecfidera. Teva would pay Biogen a royalty on sales of the Teva AG. Biogen provided a launch notice to Teva designating September 15, 2020 as the launch date for the authorized generic of Tecfidera.

404. Teva launched in September 2020 and, by the end of 2020, Biogen and Teva's AG had captured a significant share of generic Tecfidera sales. Despite this success, Biogen decided to eliminate the AG Tecfidera because of the threat that it posed to Vumerity. In March 2021, Biogen suspended the AG agreement with Teva and then, in April 2021, terminated it.

405. On May 5, 2023, Teva brought a breach of contract and unjust enrichment action against Biogen.[5] Teva alleged that Biogen terminated the agreement because generic Tecfidera was taking sales from Vumerity: "It appears that, upon realizing the full scope of competition from other generic versions of Tecfidera®, and in light of the possibility that Product sold by Teva might take sales from other medicines in its portfolio also approved for treatment of MS [i.e., Vumerity], Biogen decided to cut bait on the Product…."

[5] Case No. 23-cv-2491 (D.N.J.). On October 11, 2024, the Court denied Biogen's motion to dismiss as to Teva's breach of contract claims. ECF No. 57. This case is in discovery.

406. The threat that generic Tecfidera posed to Vumerity was so acute that Biogen even refused to permit Teva to sell the shipments of Tecfidera that Biogen had already transferred to Teva. That product expired and had to be destroyed.

407. This is yet another instance of Biogen incurring significant costs not in order to compete, but to impair the competition that otherwise would have occurred.

XI. BIOGEN'S ANTICOMPETITIVE CONDUCT SUPPRESSED GENERIC COMPETITION.

408. Biogen's comprehensive anticompetitive schemes—to impair and delay competition from generic Tecfidera and to switch the market to Vumerity—had exactly the types of anticompetitive effects that make the conduct unlawful.

409. With free and open competition, generic Tecfidera would have rapidly eroded the Tecfidera sales base. Congress, all 50 states, and the FDA have cleared the pathways for generics to enter quickly, and in force, as soon as patent barriers have been cleared away. The statutory and regulatory policy "is designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

410. Absent Biogen's conduct, generic Tecfidera would indeed have sped onto the market. As of August 2020, when the courts found Biogen's patent invalid, Tecfidera had annual sales of about $3 billion. Sales of that magnitude typically attract entry by numerous generic manufacturers, and that happened here. By October 2020, seven generic manufactuers had entered the market with generic Tecfidera.

411. The sales price of generic drugs—the price from the generic manufacturers to wholesalers and retailers—is determined by the number of manufacturers/suppliers. With seven generic manufacturers in the market, wholesale generic prices are typically competed down to a 90% discount off the brand drug within six to nine months of entry. And that happened here. By

February 2021, the manufacturers were selling generic Tecfidera to wholesalers and retailers at discounts of 89% off the price of brand Tecfidera.

412. Generic manufacturers also rapidly take unit sales away from the brand product. With just a few manufacturers in the market, and often with only one, the generics typically take more than 90% of the pre-generic-entry unit sales within the first 10 months.

413. Biogen's unlawful conduct prevented that from happening with respect to generic Tecfidera. The generics were *available* from more than a half dozen manufacturers and were *sold to wholesalers and retailers* at competitive prices. But Biogen's conduct targeted a different point in the distribution chain: despite the competitive wholesale prices, Biogen impaired the generics *actually being dispensed* to insureds.

414. As a result of Biogen's conduct, by June 2021—ten months after generic entry—generic Tecfidera had garnered less than a third of the unit sales. This compares to the typical generic penetration rate of 90+%. By June 2022, generic Tecfidera had garnered only 47%; as late as June 2024—nearly four years after generic entry—the generic sales were only 55%.

415. Given the dramatically lower prices at which generic Tecfidera was available, Biogen's impairing generic uptake caused massive harm to Plaintiffs and other health plan purchasers. Biogen's impairment of competition from generic Tecfidera during the period August 2020 to April 2024 cost purchasers more than $3 billion in lost savings.

416. Biogen's scheme to switch the market from Tecfidera to Vumerity also worked. In May 2020, before the courts invalidated Biogen's patent and it started switching the market in earnest, Vumerity had monthly unit sales of only 50,225 capsules (equal to only 419 thirty-day supplies at four capsules per day). That was just 1% of thirty-day supplies compared to Tecfidera's sales of 2,495,616 capsules (equal to 41,594 thirty-day supplies at two capsules per day). By June

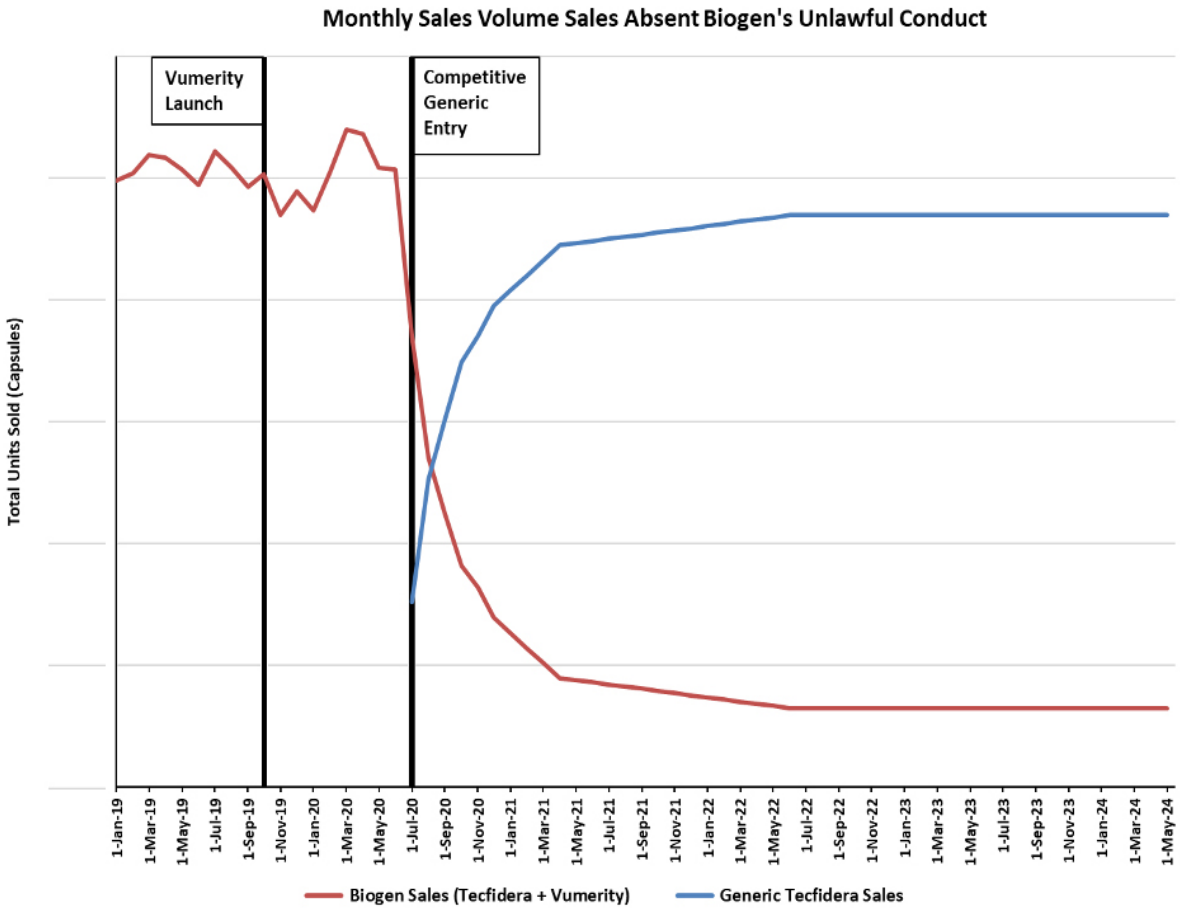
2021 Vumerity's monthly unit sales had sky-rocketed to more than 733,897 capsules (equal to 6,116 thirty-day supplies at four capsules per day). At that time, Biogen's Vumerity sales accounted for more than 29% of its combined sales of Tecfidera and Vumerity. Almost all of those sales came from prescriptions that, absent Biogen's market switch, would have been for Tecfidera and substituted with the generic.

417. Had Biogen not implemented that scheme, by June 2021, 90% or more of the relevant prescriptions would have been filled with generic Tecfidera.

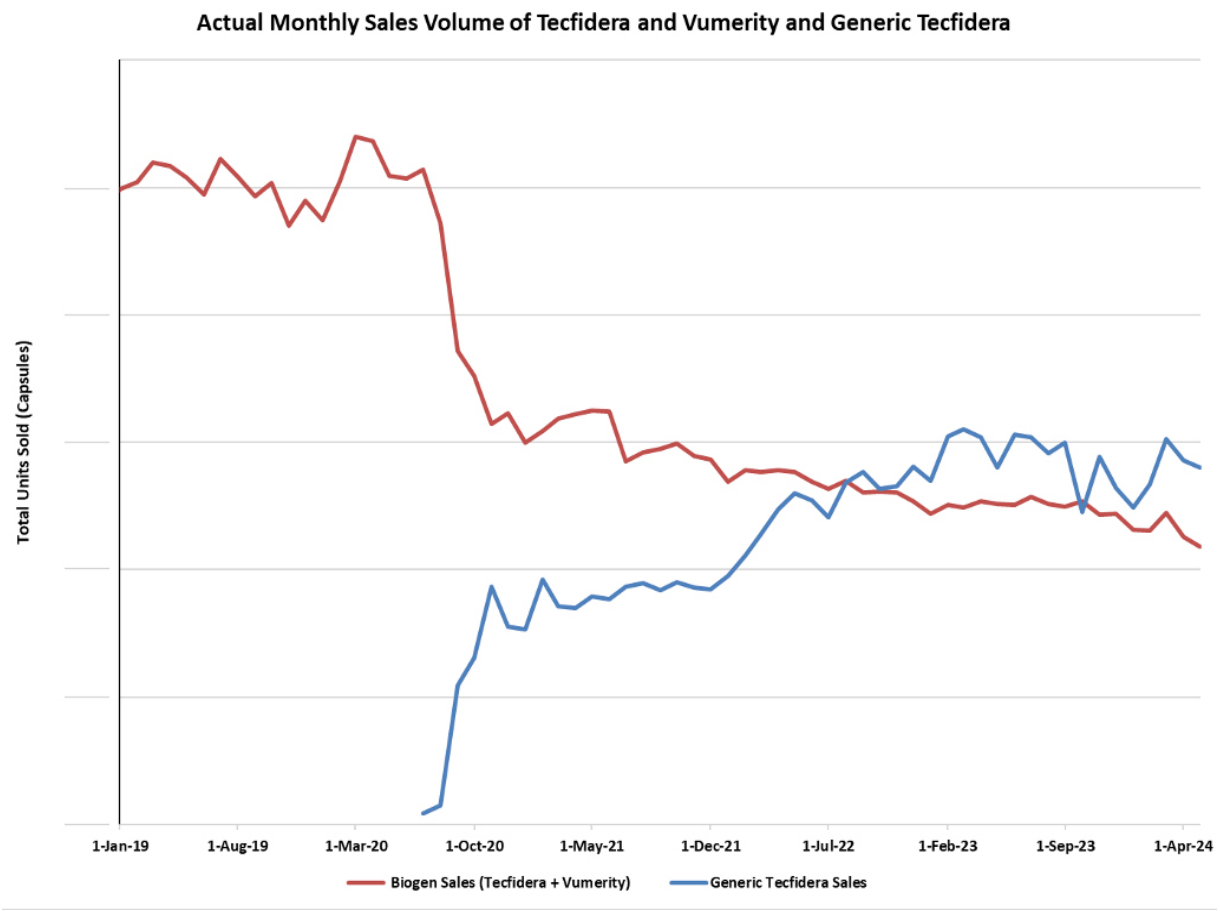
418. That conclusion is confirmed by focusing on the timeline for sales of Vumerity. Based on Vumerity's medical merit—that is, its *lack* of substantial improvement over Tecfidera—without Biogen's scheme Vumerity would have achieved unit sales of less than 5% of the monthly unit sales that branded Tecfidera had in July 2020.

419. That very modest sales figure for Vumerity is readily confirmed by the lack of superiority of Vumerity over Tecfidera and its generic equivalents. Just as Biogen intended, its unlawful conduct significantly and artificially inflated the sales of both Tecfidera and Vumerity. Those sales came at the expense of the dramatically less expensive generic Tecfidera.

420. Absent Biogen's unlawful conduct, its combined unit sales of branded Tecfidera and Vumerity, compared to sales of generic Tecfidera, would have looked approximately like this:



421. As a result of Biogen's payoffs to the PBMs and other anticompetitive conduct, its actual combined unit sales of branded Tecfidera and Vumerity during that same timeframe, compared to sales of generic Tecfidera, looked approximately like this:



422. Moreover, this chart includes as "generic" sales the portion of sales made by a generic manufacturer to a mail order or specialty pharmacy (directly or indirectly) but that the pharmacy then sold to Plaintiffs and other health plans at the outrageous "specialty drug" prices. As noted above (see Section XIII(B)(2)), in exchange for Biogen's rebates and fees, the Co-Conspirators designated more than 60% of all generic units as a "specialty drug."

423. So the rate of sales of *true* low-cost generics—not including the high-cost "generics" that Biogen paid to have designated as "special"—was even lower than reflected in the graph immediately above. The units actually priced to health plans *as real generics* accounted for an even more miserable 17% of total units (Tecfidera, Vumerity, and all generics) in June 2021

and 24% in June 2022. Absent Biogen's unlawful conduct, that rate would have been 90+% by June 2021.

424. To overcome the price disconnect in pharmaceutical markets, Congress and every State promote the distribution of generic drugs through automatic substitution at the pharmacy counter. That automatic substitution is generic manufacturers' cost-efficient means of competing. Biogen's payoff-enabled market switch substantially impaired generic manufacturers' cost-efficient means of competing, and deprived health plans and insureds of the benefits of that competition.

425. Biogen's unlawful conduct substantially foreclosed generic competition by denying generic manufacturers a fair opportunity to compete using state generic-substitution laws. Biogen's kickback-enabled campaign to switch patients to Vumerity effectively coerced patients and Class members to purchase brand Tecfidera and Vumerity despite the availability of more affordable generic Tecfidera.

426. Only brand manufacturers—not generic manufacturers—pay rebates and fees to PBMs. So the PBMs shared Biogen's incentive to have as many prescriptions as possible switched from Tecfidera to Vumerity, not to the generic. The PBMs will go on collecting rebates and fees on Vumerity into the future—the patents on Vumerity do not expire until 2033.

427. Manufacturers do not pay any rebates or fees to PBMs on generic Tecfidera. The economic benefits of generic Tecfidera flow to actual drug purchasers, not to the PBMs.

428. Those losses from the market-switch scheme continue to pile up, and will go on piling up absent effective injunctive relief from this Court. As of May 2024, Vumerity has a sales base of more than a million units per month. No generic is available for that product. Absent

Biogen's unlawful conduct, Vumerity would have a prescription base of less than 200,000 units per month.

429. Bottom line: health plans and insureds are paying for the difference. They are paying for more than 800,000 units per month for branded Vumerity that, absent Biogen's unlawful conduct, would have been filled with generic Tecfidera. The difference in cost for the brand Vumerity versus generic Tecifidera for those prescriptions is a staggering $655 million per year. Absent effective injunctive relief, those overcharges could continue until 2033.

430. Moreover, those two elements of loss—the initial overcharges of more than $3 billion for the period August 2020 to April 2024, and the ongoing overcharges of $655 million per year—do not account for all of the losses. The economic losses from designating generic Tecfidera as a specialty drug are not included in those amounts. The specialty drug part of the scam has already cost health plans more than an estimated $1 billion. Those losses, too, are continuing.

XII. THE SCHEME'S ANTICOMPETITIVE EFFECTS

431. Biogen's scheme and payments to suppress generic competition to Tecfidera have delayed and substantially diminished the sale of generic Tecfidera. By delaying the onset of full generic competition and decimating the prescription base, Biogen deprived would-be generic manufacturers of the most efficient means of distribution under the governing statutes and regulations.

432. Biogen's anticompetitive conduct, and the PBMs' participation in it, delayed and substantially diminished the sale of generic Tecfidera in the United States, and unlawfully enabled Biogen to sell Tecfidera and Vumerity at artificially inflated units and prices. But for Biogen's illegal conduct, generic manufacturers would have been able to enter the market unimpeded and compete on the merits against Tecfidera and Vumerity. Biogen's conduct unlawfully prevented

purchasers of Tecfidera and Vumerity from obtaining the benefits of unimpaired generic competition.

433. Biogen's scheme and unlawful payments harmed Plaintiffs and the Class by depriving them of a market in which: (1) the prescription base available for automatic generic substitution is determined by unrestrained competition; (2) they receive the honest services of PBMs, untainted by kickbacks for promoting higher-priced branded drugs rather than generics; (3) generic drug manufacturers have unimpaired access to the most cost efficient means of distribution; (4) follow-on branded products compete on the merits, unaided by kickbacks that enable and facilitate a market switch designed to impair generic competition; and (5) PBMs do not designate generic drugs as "specialty drugs" at the behest of competing brand manufacturers.

434. But for Biogen's unlawful conduct: (1) by June 2021 about 90% of prescriptions for Tecfidera would have been filled with the much less expensive generic Tecfidera; (2) Biogen would have been able to switch few Tecfidera prescriptions to Vumerity; and (3) the Co-Conspirator PBMs would not have designated generic Tecfidera as a specialty drug.

435. Biogen's unlawful conduct has delayed and diminished the sale of generic Tecfidera in the United States, and unlawfully enabled Biogen to sell Tecfidera and Vumerity at artificially inflated, supracompetitive prices, and unlawfully caused a substantial portion of generic Tecfidera to be sold at supracompetitive prices. As a consequence, Plaintiffs and other Class members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

XIII. CLASS ACTION ALLEGATIONS

436. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), 23(b)(2), and (b)(3), as representatives of Classes defined as follows:

a. The Health Plan Class:

> All entities that purchased, paid and/or provided reimbursement for some or all of the purchase price of Vumerity, Tecfidera, and/or its AB-rated generic equivalents in any form, in the United States and its territories, for consumption by their members, insureds, or beneficiaries, other than for resale, during the period August 19, 2020 through and until the anticompetitive effects of Biogen's unlawful conduct cease (the "Class Period").

b. The RICO Sub-Class:

> All employee welfare benefit plans that: (1) received services from one or more Co-Conspirator PBMs; and (2) purchased, paid and/or provided reimbursement for some or all of the purchase price of Vumerity, Tecfidera, and/or its AB-rated generic equivalents in any form, in the United States and its territories, for consumption by their members, insureds, or beneficiaries, other than for resale, during the period August 19, 2020 through and until the anticompetitive effects of Biogen's unlawful conduct cease (the "Class Period").

437. The following persons or entities are excluded from each of the proposed Classes:

a. Defendant and its co-conspirators named herein, and their management, subsidiaries, or affiliates; and

b. All federal or state governmental entities.

As to both classes:

438. Class members are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes thousands of third-party payors.

439. Plaintiffs' claims are typical of those of the Class members. Plaintiffs and all Class members were damaged by the same wrongful conduct of Biogen, i.e., they paid artificially inflated prices for Tecfidera and Vumerity and were deprived of the benefits of more robust competition from cheaper generic versions of Tecfidera as a result of Biogen's wrongful conduct.

440. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

441. Plaintiffs are represented by counsel with experience in the prosecuting class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

442. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members because Biogen has acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Biogen's wrongful conduct.

443. As to the Health Plan Class, questions of law and fact common to the Class include, but are not limited to:

a. whether Biogen conspired to suppress generic competition to Tecfidera;

b. whether Biogen and one or more of the Co-Conspirator PBMs entered into an unlawful agreement in restraint of trade;

c. whether, pursuant to the agreement, one or more of the Co-Conspirator PBMs agreed to disfavor generic Tecfidera on its formularies;

d. whether, pursuant to the agreement, one or more of the Co-Conspirator PBMs designated generic Tecfidera as a specialty drug;

e. whether, pursuant to the agreement, one or more of the Co-Conspirator PBMs imposed step edits and prior authorizations for generic Tecfidera;

f. whether, pursuant to the agreement, Biogen compensated the Co-Conspirator PBM;

g. whether Biogen's compensation to the Co-Conspirator PBM was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

h. whether the agreement is illegal under the rule of reason;

i. whether Biogen provided coupons to patients to impair price signals as between Tecfidera and generic Tecfidera;

j. whether Biogen provided coupons to patients to impair price signals as between Vumerity and generic Tecfidera;

k. whether Biogen switched the market from Tecfidera to Vumerity in order to impair competition from generic Tecfidera;

l. whether one or more of the Co-Conspirator PBMs had significant control and discretion over the classification and disclosure of payments received from Biogen;

m. whether Plaintiffs and Class members reasonably trusted and relied on their PBMs to exercise their discretion in classifying and disclosing payments from Biogen;

n. whether Biogen knowingly made payments to one or more of the Co-Conspirator PBMs and its affiliated aggregators that were conditioned on the PBMs not advantaging lower cost generic Tecfidera over Tecfidera and Vumerity on plan formularies;

o. whether Biogen made those payments so that it could continue charging excessive and supracompetitive prices for Tecfidera and Vumerity by limiting competition from generic Tecfidera;

p. whether Biogen and one or more of the Co-Conspirator PBMs knew that Biogen's payments were made in exchange for making formulary decisions or modifications that would increase, not reduce, the costs for the PBM's health plan clients;

q. whether, by accepting and keeping Biogen's payments in exchange for impairing generic Tecfidera, one or more of the Co-Conspirator PBMs violated its fiduciary duty or duty of fidelity or obligation owed to its health-plan clients;

r. whether Biogen's payments to one or more of the Co-Conspirator PBMs were conditioned on disadvantaging generic Tecfidera on the PBMs' formularies and were therefore commercial bribes in violation of Section 2(c) of the Robinson-Patman Act;

s. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

t. whether Biogen's conduct as alleged herein has substantially affected interstate commerce;

u. whether, and to what extent, Biogen's conduct caused antitrust injury (i.e., overcharges) to Plaintiffs and the Class members; and

v. the quantum of aggregate overcharge damages to the Class.

444. As to the RICO Sub-Class, questions of law and fact common to the Class include, but are not limited to:

a. whether Biogen formed associations-in-fact enterprises with one or more of Express Scripts, CVS Caremark, OptumRx, HPS, and MHS;

b. whether, in violation of Section 1954, Biogen made payments to one or more of the Co-Conspirator PBMs with the intent to influence it with respect to the formulary management services that it provides to Plaintiffs and other health plans;

c. whether Biogen systematically paid bribes and kickbacks—falsely labeled as rebates, administrative fees, or other payments—to one or more of the Co-Conspirator PBMs in exchange for it not favoring generic Tecfidera over Tecfidera and Vumerity on their formularies;

d. whether one or more of the Biogen-PBM Pricing Enterprises involved coordinated efforts between Biogen and the Co-Conspirator PBM;

e. whether the bribery scheme that corrupted one or more of the Biogen-PBM Pricing Enterprises was mutually beneficial to Biogen and the Co-Conspirator PBM;

f. whether one or more of the Biogen-PBM Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Biogen and the Co-Conspirator PBM;

g. whether one or more of the Biogen-PBM Pricing Enterprises functions as a continuing unit and has been operated for the purposes of carrying out the bribery and kickback scheme and its concealment;

h. whether one or more of the RICO enterprises also has an ascertainable structure distinct from the pattern of racketeering activities of the RICO enterprise;

i. whether Biogen and one or more of the Co-Conspirator PBMs have acted in concert to corrupt what was previously a legitimate business relationship between Biogen and the PBM;

j. whether Biogen violated 18 U.S.C. § 1954(4) when it made a payment to a Co-Conspirator PBM with the intent to influence the PBM not to prefer lower-cost generic Tecfidera over higher-cost Tecfidera and Vumerity on the PBM's formularies;

k. whether one or more of the Co-Conspirator PBMs violated 18 U.S.C. § 1954(4) when the PBM received a payment from Biogen with the intent to be influenced with respect to its actions, decisions, or other duties relating to ERISA plans;

l. whether Biogen's and one or more of the Co-Conspirator PBMs' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and Class members to be injured in their business or property; and

m. the quantum of aggregate damages to the Class.

As to both Classes:

445. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

446. Biogen's anticompetitive and unlawful conduct has imposed and will continue to impose (unless the Court grants effective equitable relief) a common antitrust injury on Plaintiffs and all Class members. Biogen's anticompetitive and unlawful conduct and its relationships with the Class members have been substantially uniform. Biogen has acted and refused to act on grounds that apply to the Class generally, and injunctive and other equitable relief is appropriate respecting the Class as a whole.

447. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XIV. INTERSTATE AND INTRASTATE COMMERCE

448. At all material times, Biogen manufactured, marketed, promoted, distributed, and sold substantial amounts of Tecfidera and Vumerity in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

449. At all material times, Biogen transmitted funds, as well as contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Tecfidera and Vumerity and/or their AB-rated bioequivalents.

450. In furtherance of its efforts to restrain competition with respect to Tecfidera and Vumerity, Biogen employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. Biogen's activities were within the flow of and have substantially affected interstate commerce.

451. Biogen's anticompetitive conduct has substantial intrastate effects in that, among other things, purchasers within each state were impaired in buying less expensive generic Tecfidera within the state. The impairment of competition from generic Tecfidera directly impacts and disrupts commerce for purchases and sales within each state.

452. Biogen produces, manufactures, distributes, and sells Tecfidera and Vumerity throughout the United States through means of interstate commerce. Biogen sold and shipped substantial quantities of Tecfidera and Vumerity in a continuous and uninterrupted flow in interstate commerce to customers located throughout the United States. The PBMs placed Tecfidera and Vumerity on their formularies in interstate commerce and sold Tecfidera and Vumerity, directly and/or through their affiliated specialty pharmacies, in interstate commerce.

453. Biogen's business activities at issue in this Complaint were within the flow of, and substantially affected, interstate trade and commerce, as commerce is defined in Section 1 of the Clayton Act, 15 U.S.C. § 12(a). Likewise, Biogen and the Co-Conspirator PBMs were engaged in interstate commerce when they participated in the bribery scheme described in this Complaint, and Biogen's and the Co-Conspirator PBMs' activities affected interstate commerce, as required under 18 U.S.C. § 1962(c).

XV. MARKET POWER AND MARKET DEFINITION

454. Biogen had the ability to control the prices of fumarate and exclude relevant competitors. Direct evidence of Biogen's market power includes the following: (a) from 2013 through the present Biogen's per-unit manufacturing cost for fumarate has been less than 15% of

the net price of the drug, *i.e.,* the price after adjusting for rebates and discounts; (b) Biogen never lowered the price of fumarate to the competitive level in response to pricing of other brand or generic drugs; and (c) from launch in April 2013 to June 2020, Biogen profitably raised the price of Tecfidera by approximately 79%. During that period, the Consumer Price Index rose by only 10.7%.

455. To the extent that Plaintiffs are required to prove market power by defining a relevant product market, Plaintiffs allege that, for the purpose of evaluating the competitive effect of Biogen's conduct, the relevant product market is the market for Tecfidera, Vumerity, and their AB-rated generic equivalents (collectively, "fumarate") and narrower markets therein. At all relevant times, Biogen had market power in the fumarate market because it had the power to raise or maintain the price of fumarate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

456. A small but significant, non-transitory increase in the competitive price of fumarate did not cause a significant loss of sales. At competitive prices, Biogen's fumarate does not exhibit significant, positive, cross-elasticity of demand with respect to price with any MS drug other than AB-rated generic Tecfidera.

457. Biogen needed to control only fumarate, and no other products, in order to maintain the price of fumarate products profitably at supracompetitive prices. Only the unimpaired market entry of a competing, AB-rated generic version of Tecfidera would render Biogen unable to profitably maintain supracompetitive prices for those products.

458. Doctors generally select MS drugs for their patients based on the clinical and pharmacological attributes of the drug and the patients' relevant characteristics, rather than principally on price. For clinical reasons, among others, physicians and patients prefer fumarate to

other MS drugs for certain patients. Due to, among other reasons, its use and effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions fumarate is significantly differentiated from all products other than AB-rated generic Tecfidera.

459. Fumarate's medical and clinical attributes significantly differentiate it from other MS drugs. Other MS drugs have different chemical compounds and formulations, and the FDA does not consider them to be interchangeable with fumarate.

460. Fumarate is the most frequently prescribed oral MS drug in the world. Most other pharmaceutical treatment options require intravenous infusions—Natalizumab (Tysabri) and Ocrelizumab (Ocrevus)—or injections—Interferon beta-1a (Avonex), Interferon beta-1b (Betaseron), and Glatiramer acetate (Copaxone). And all of these IV infusions and injectables have much worse side-effect profiles than fumarate. These include skin reactions or infection at the infusion or injection site, fatigue, muscle weakness, flu-like symptoms, headache, fever, nausea, and joint pain.

461. Teriflunomide (Aubagio) is an orally administered MS drug, but it causes diarrhea, nausea, hair loss, and liver problems. In contrast, the most common side effects for fumarate are flushing and gastrointestinal upset. Those side effects are easily mitigated by taking the medication with food or aspirin.

462. Biogen advised its investors in April 2020 that the entry of another MS drug pill, Banner's Bafiertam, would not "significant[ly] impact" Tecfidera's sales. Bafiertam is monomethyl fumarate, which produces the same active metabolite as Tecfidera. Biogen explained that despite the chemical similarities, Bafiertam would not significantly affect Tecfidera's sales because Bafiertam "is not a directly substitutable A/B product."

463. Biogen's statement proved to be accurate. As of May 2024, Bafiertam sells only approximately 46,000 capsules per month (383 thirty-day supplies at 4 capsules per day). Less than 2% of the combined dimethyl, monomethyl, and diroximel fumarate unit sales are of Bafiertam.

464. At all relevant times, Biogen enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of drug development, entry, and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

465. Until July 2020, Biogen's market share in the relevant market was 100%. From July 2020 through the present its dollar share of the market has exceeded 85%, and its unit share has been as high as 95% and has always exceeded 45%. Biogen's anticompetitive conduct has shielded approximately 800,000 monthly unit sales of fumarate from generic competition.

466. The United States and its territories and/or and narrower markets therein, constitute the relevant geographic market.

467. Biogen's market power with respect to fumarate was substantial—it was monopoly power.

XVI. MARKET EFFECTS AND DAMAGE TO THE CLASSES

468. Biogen's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting its fumarate products from generic competition. That conduct has caused Plaintiffs and the Classes to pay more than they would have paid for fumarate absent Biogen's illegal conduct.

469. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, health

plans and insureds rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in impairing generic competition, and purchasers experience substantial cost inflation from that impairment.

470. But for Biogen's anticompetitive conduct, Plaintiffs and Class members would have paid less for fumarate because, among other reasons, they would have: (a) substituted more purchases of less-expensive AB-rated generic Tecfidera for their purchases of more-expensive branded Tecfidera; (b) received lower prices for their few purchases of branded Tecfidera; (c) substituted more purchases of less-expensive AB-rated generic Tecfidera for the prescriptions that Biogen switched from Tecfidera to Vumerity; (d) paid far less for their purchases of AB-rated generic Tecfidera; and (e) paid less for their few purchases of Vumerity.

471. During the Class Period, Plaintiffs and other Class members purchased substantial amounts of Biogen's fumarate. As a result of Biogen's illegal conduct, Plaintiffs and other Class members were compelled to pay, and did pay, artificially inflated prices for Biogen's fumarate drugs. Plaintiffs and the other Class members paid prices for Biogen's fumarate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because they: (1) were deprived of the opportunity to purchase lower-priced generic Tecfidera instead of expensive brand Tecfidera and/or brand Vumerity; (2) paid artificially inflated prices for Tecfidera and Vumerity; and (c) paid artificially inflated prices for generic Tecfidera.

472. As a consequence, Plaintiffs and other Class members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

XVII. ANTITRUST IMPACT

473. During the relevant period, Plaintiffs and Class members purchased substantial amounts of Tecfidera, generic Tecfidera and/or Vumerity directly from Biogen or its co-conspiring specialty pharmacies and/or indirectly from others, other than for resale. As a result of Biogen's illegal conduct, Plaintiffs and Class members were compelled to pay, and did pay, artificially inflated prices for their fumarate requirements.

474. Overcharges at a higher level of distribution generally result in higher prices at every level below. Wholesalers and retailers passed on the inflated prices of fumarate drugs to Plaintiffs and Class members, and the co-conspiring specialty pharmacies directly charged inflated prices to Plaintiffs and Class members.

475. Biogen's anticompetitive conduct allowed it to charge health plans and insureds prices in excess of what Biogen otherwise would have been able to charge absent Biogen's anticompetitive conduct. Another purpose and effect of Biogen's anticompetitive conduct was to enable the PBM-affiliated co-conspiring specialty pharmacies to charge health plans and insureds prices in excess of what those pharmacies otherwise would have been able to charge.

476. The prices were inflated as a direct, foreseeable, and intended result of Biogen's anticompetitive conduct. The inflated prices that Plaintiffs and Class members paid are traceable to, and the foreseeable result of, the overcharges that Biogen's conduct caused.

477. Biogen's unlawful conduct deprived Plaintiffs and the Classes of the benefits of competition that the antitrust laws were designed to ensure, and their injuries flow from that which makes Biogen's conduct unlawful.

XVIII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

478. In accordance with the requirements of Arizona Revised Statute § 44-1415; Conn. Gen. Stat. Ann. § 35-37; Mass. Gen. Laws Ann. ch. 93A, § 10; Minn. Stat. § 325D.63; Nevada Revised Statute § 598A.210(3); Or. Rev. Stat. § 646.780(5)(b); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or about August 16, 2024, September 20, 25 and 26, 2024, counsel for Plaintiffs sent letters regarding this class-action litigation to the Attorneys General of Arizona, Connecticut, Massachusetts, Minnesota, Nevada, Oregon, Rhode Island, and Utah. The letters informed the Attorneys General of the existence of Plaintiffs' lawsuits, identified the relevant state antitrust provisions at issue, and enclosed a copy of their initial complaints.

479. On or about August 15, 2024, September 20, 25, and 27, 2024, counsel for Plaintiffs sent demand letters to Biogen regarding this class-action litigation, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., Massachusetts). The demand letters identified the claimants as Plaintiffs, in their individual and representative capacity; described the allegedly unfair or deceptive acts or practices that Biogen committed (i.e., its efforts to suppress competition from generic Tecfidera); described Plaintiffs' and Class members' injury (increased prices for fumarate); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XIX. CLAIMS FOR RELIEF

CLAIM ONE
VIOLATION OF 15 U.S.C. § 1
CONTRACT IN RESTRAINT OF TRADE

480. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

481. At all relevant times, Biogen possessed market power in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

482. Biogen entered into agreements with each of the five PBMs pursuant to which it agreed to pay, and did pay, substantial kickbacks to each of them in exchange for their reciprocal agreement to disadvantage generic Tecfidera on their formularies and/or to limit distribution of generic Tecfidera to specialty pharmacies. Biogen made each of the agreements with the purpose and effect of impairing generic competition and buying time for Biogen to switch the market from Tecfidera to Vumerity.

483. The purpose and effect of the payments that Biogen made to the five PBMs under the agreements was to substantially impair competition from generic Tecfidera. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments and restrictions on competition that outweighs the harmful effects of the payments and restrictions on competition. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

484. The agreements, individually and collectively, covered a sufficiently substantial percentage of the relevant commerce to harm competition.

485. As a direct and proximate result of Biogen's unlawful restraint of trade, Plaintiffs and Class members paid artificially inflated prices for fumarate and were harmed as a result.

486. Plaintiffs and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the Sherman Antitrust Act, 15 U.S.C. § 1, was designed to prevent, and flow from that which makes Biogen's conduct unlawful.

487. Plaintiffs and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's anticompetitive conduct.

CLAIM TWO
VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE

488. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

489. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

490. Biogen conspired with the PBMs and their specialty pharmacies to create and maintain a monopoly in the market for fumarate. Biogen, the Coconspirator PBMs, and their specialty pharmacies engaged in anticompetitive conduct in furtherance of the conspiracy to maintain its monopoly, which included, cumulatively and in the alternative: (a) agreeing to pay and paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies; (b) agreeing to pay and paying one or more of the five PBMs to limit distribution of generic Tecfidera to specialty pharmacies; (c) making those payments knowing that the PBMs owed a fiduciary duty to their health-plan clients and that they hid some or all of the payments from their clients and funneled some or all of the payments to offshore affiliates; (d) engaging in this conduct in order to impair generic competition and to switch the market from Tecfidera to Vumerity; (e)

entering into agreements that caused Plaintiffs and Class members to be required to purchase Tecfidera, Vumerity, and generic Tecfidera from the PBM-owned specialty pharmacies at supracompetitive prices; and (f) conspiring to impair generic competition and suppress sales of lower cost generic Tecfidera.

491. Through Biogen's conspiracy to monopolize, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

492. The goal, purpose and effect of the Biogen-directed conspiracy was and is to maintain and extend Biogen's monopoly over the relevant market by and through the anticompetitive conduct in furtherance of the conspiracy described above.

493. Biogen's conspiracy to monopolize harmed competition and purchasers as alleged above.

494. There are no non-pretextual procompetitive justifications for Biogen's conspiracy to monopolize. Even if there were such a conceivable justification, the conspiracy's anticompetitive effects far outweigh any conceivable justification. Further, the conspiracy to monopolize was far broader than necessary to achieve any conceivable procompetitive benefit.

495. Biogen's conspiracy to monopolize was the direct and proximate cause of the injuries to Plaintiffs and Class members.

496. Plaintiffs and the Class members have been injured in their business or property as a direct and proximate result of Biogen's conspiracy to monopolize, and their injuries are the type that the Sherman Antitrust Act, 15 U.S.C. § 2, was designed to prevent, and flow from that which makes Biogen's conduct unlawful.

497. By engaging in the foregoing anticompetitive conduct, Biogen has intentionally and wrongfully conspired to monopolize in violation of the Sherman Act.

498. Plaintiffs and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's conspiracy to monopolize.

CLAIM THREE
VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION

499. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

500. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

501. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate by switching the market from Tecfidera to Vumerity through coercive means. Biogen's anticompetitive scheme included, cumulatively and in the alternative:

(a) concocting the false claim that Vumerity is medically superior to Tecfidera;

(b) pervasively marketing the false claim that Vumerity is medically superior to Tecfidera;

(c) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Vumerity;

(d) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which Vumerity is subject;

(e) providing patient coupons to insured, with the purpose and effect of eliminating accurate price signals as to the relative costs of Vumerity and generic Tecfidera;

(f) linking rebates and fees on Tecfidera to better formulary placement of Vumerity; and

(g) directly reducing the supply of generic Tecfidera.

502. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

503. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

504. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

505. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

506. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiffs and Class members.

507. Plaintiffs and the Class members have been injured in their business or property as a direct and proximate result of Biogen's anticompetitive conduct, and their injuries are the type that the statutes were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

508. Plaintiffs and the Class members seek damages and treble damages as permitted by law for the injuries they suffered as a result of the Biogen's anticompetitive conduct.

CLAIM FOUR
VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION

509. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

510. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

511. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate. Biogen's anticompetitive scheme included, cumulatively and in the alternative:

(a) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Tecfidera;

(b) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Vumerity;

(c) paying one or more of the five PBMs to limit distribution of generic Tecfidera to specialty pharmacies;

(d) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which branded Tecfidera is subject;

(e) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which Vumerity is subject;

(f) providing patient coupons to insureds, with the purpose and effect of eliminating accurate price signals as to the relative costs of generic Tecfidera and Tecfidera;

(g) providing patient coupons to insureds, with the purpose and effect of eliminating accurate price signals as to the relative costs of generic Tecfidera and Vumerity;

(h) anticompetitively switching prescriptions from Tecfidera to Vumerity through coercive anad unlawful means;

(i) concocting the false claim that Vumerity is medically superior to Tecfidera;

(j) pervasively marketing the false claim that Vumerity is medically superior to Tecfidera;

(k) linking rebates and fees on Tecfidera to better formulary placement of Vumerity; and

(l) directly reducing the supply of generic Tecfidera.

512. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

513. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

514. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

515. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

516. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiffs and Class members.

517. Plaintiffs and the Class members have been injured in their business or property as a direct and proximate result of Biogen's anticompetitive conduct, and their injuries are the type that the statutes were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

518. Plaintiffs and the Class members seek damages and treble damages as permitted by law for the injuries they suffered as a result of the Biogen's anticompetitive conduct.

CLAIM FIVE
VIOLATION OF 15 U.S.C. § 13(c)
COMMERCIAL BRIBERY

519. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

520. Commercial bribery violates Section 2(c) of the Robinson-Patman Act. As described in this Complaint, Biogen engaged in a commercial bribery scheme relating to the sale of fumarate drug products in the United States.

521. PBMs have, and hold themselves out as having, superior knowledge and expertise about price negotiations with brand-drug manufacturers and the use of formularies to reduce the cost of prescription drugs. PBMs tout that superior knowledge and expertise to obtain the business of health plans, and PBMs know that health plans lack the resources or pharmaceutical expertise

necessary to negotiate with drugmakers directly and develop their own formularies. Further, the PBMs' superior knowledge includes information about drug manufacturer pricing, rebates and discounts that is not publicly available. Because of the PBMs' superior knowledge and expertise, health plans retain PBMs to negotiate with Biogen and other drug manufacturers on their behalf.

522. Plaintiffs, Class members, and the PBMs they retained all understood that the purpose of retaining a PBM was to assist health plans with reducing the plans' costs associated with providing prescription drug benefits to insureds. Plaintiffs and Class members trusted their PBMs to make formulary placement decisions, including for generic Tecfidera, Tecfidera, and Vumerity, that served the interests of their health plan clients.

523. Plaintiffs and Class members trusted their PBMs because the PBMs invited their reliance, trust, and confidence. The PBMs invited the health plans' reliance, trust, and confidence not only through the PBM's expertise and specialized knowledge, but also because of how the PBMs held themselves out to their health plan clients and the public. PBMs tell their health plan clients and the public that PBMs' interests are aligned with the health plans they serve. PBMs also tell their health plan clients and the public that they help health plans reduce the costs associated with providing prescription drugs to plan subscribers, including by using their formularies to promote the use of low-cost generics and biosimilars over their high-cost branded counterparts. Health plans therefore rely on PBMs to control decisions about formulary inclusion and placement, especially with respect to individual drugs trusting that the PBMs will use their skill, knowledge, and influence in the prescription drug industry to lower their clients' prescription drug costs.

524. In addition to retaining and trusting PBMs to handle formulary management for them, PBMs also had significant control and discretion over the classification and disclosure of payments received from drug manufacturers in the course of negotiations for formulary placement.

For example, PBMs had the discretion to characterize payments from drug manufacturers, including Biogen, as "fees" instead of "rebates" to avoid disclosing those payments to, or sharing them with, their health plan clients. PBMs also had the discretion to use rebate aggregators instead of receiving payments directly from drug manufacturers, including Biogen, to avoid disclosing those payments to, or sharing them with, their health plan clients. Plaintiffs and Class members reasonably trusted and relied on their PBMs to exercise their discretion in classifying and disclosing drugmaker payments for the benefit of the PBMs' health plan clients. Plaintiffs and Class members reasonably did not expect PBMs to exercise that discretion to harm their health plan clients, as occurred in the Biogen/PBM bribery scheme described in this Complaint.

525. Taken together, the foregoing circumstances—which include the invited reliance, trust, and confidence that health plans give to PBMs in formulary management and the PBMs' discretion with respect to disclosing and sharing drugmaker payments—give rise to a common law fiduciary duty or duty of fidelity owed by PBMs to their health plan clients, including Plaintiffs and Class members.

526. When Biogen negotiates with a PBM regarding the price of Tecfidera or Vumerity, Biogen knows that the PBM is negotiating on behalf of the PBM's health-plan clients who are purchasing those drugs for their plan members.

527. Biogen knowingly made payments to the PBMs and their affiliated aggregators that were conditioned on the PBMs not advantaging lower cost generic Tecfidera over Tecfidera and Vumerity on plan formularies. Biogen made those payments so that Biogen could continue charging excessive and supracompetitive prices for Tecfidera and Vumerity by limiting competition from generic Tecfidera. Biogen knew that these rebates and fees were actually

commercial bribes and that the PBMs would retain some or all of the payments for themselves and would not disclose the retained portion of the payment to their clients, the plans.

528. Biogen and the PBMs all knew that Biogen's payments were made in exchange for making formulary decisions or modifications that would increase, not reduce, the costs for the PBMs' health plan clients.

529. The PBMs kept some or all of Biogen's payments for themselves. Moreover, the PBMs did not disclose to their health-plan clients that the PBMs had received payments from Biogen in exchange for impairing competition from generic Tecfidera, or that Biogen and the PBMs were impairing that competition in the service of switching the market from Tecfidera to Vumerity.

530. By accepting and keeping Biogen's payments in exchange for impairing generic Tecfidera, the PBMs violated their fiduciary duty or duty of fidelity or obligation owed to their health-plan clients. Impairing generic Tecfidera raised their health plan clients' costs, which was the opposite of what the health plans trusted the PBMs to do for them.

531. There is no legitimate business justification for impairing generic Tecfidera. Generic Tecfidera produces the same active ingredient as Tecfidera and Vumerity, and generic Tecfidera is substantially less costly than Tecfidera and Vumerity.

532. Biogen's payments to PBMs were conditioned on disadvantaging generic Tecfidera on the PBMs' formularies and were therefore commercial bribes in violation of Section 2(c) of the Robinson-Patman Act.

533. Had Biogen not bribed the PBMs, the PBMs would have given generic Tecfidera more favorable placement on their formularies to promote the use of generic Tecfidera over the higher-cost Tecfidera and Vumerity. Favorable placement on the PBMs' formularies for generic

Tecfidera would have resulted in a significant shift in sales to the lower-cost generic Tecfidera from the higher-cost Tecfidera and Vumerity.

534. Biogen's bribery scheme has corrupted what should be legitimate negotiations between PBMs and drug manufacturers to reduce the costs associated with administering prescription drug benefits. As the PBMs themselves as have said publicly, the proper role of PBMs is to use formulary placement decisions to generate competition among manufacturers of drugs with similar applications. By awarding more favorable formulary placement to the least costly drug, PBMs create incentives for drug manufacturers to become the lowest-cost provider.

535. In contrast, Biogen made payments to the PBMs with the intent of improperly influencing or corrupting the PBMs' process of awarding favorable formulary placement to low-cost products over higher-cost alternatives. Biogen used those payments to significantly impair competition from generic Tecfidera, the lowest-cost option, while promoting the use of higher-cost Tecfidera and Vumerity. In this scheme, Biogen and the PBMs benefitted at the expense of Plaintiffs and Class members while impairing competition in the relevant market.

536. Plaintiffs and Class members were injured by Biogen's bribery scheme because they paid supracompetitive prices for fumarate. Plaintiffs therefore have suffered substantial damages in the form of overcharges on fumarate. Plaintiffs' and the Class members' injury is the type of injury that the antitrust laws were designed to prevent and flows from the anticompetitive effects that make Biogen's acts unlawful.

537. Plaintiffs and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's anticompetitive conduct.

CLAIM SIX
VIOLATION OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO), 18 U.S.C. § 1962(c)

538. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

539. Plaintiffs bring this count against Biogen on behalf of themselves and the Classes and allege violations of 18 U.S.C. § 1962(c), which makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."

540. Biogen and each of the Co-Conspirator PBMs are "persons," as that term is defined in 18 U.S.C. § 1961(3).

541. As discussed below, Biogen formed associations-in-fact enterprises with each of Express Scripts, CVS Caremark, Optum Rx, HPS, and MHS. Biogen and the Co-Conspirator PBMs have conducted or participated in the conduct of their respective enterprises' affairs through a pattern of racketeering activity that directly caused Plaintiffs and Class members to incur higher costs for purchasing fumarate drugs. The predicate acts for this RICO count are Biogen's and the Co-Conspirator PBMs' violations of 18 U.S.C. § 1954, which prohibits the payment and receipt of bribes, kickbacks, or other conflict-of-interest payments to organizations that provide services to ERISA plans. Under 18 U.S.C. § 1954(4) ("Section 1954"), it is unlawful to directly or indirectly give or offer such a fee, kickback, commission, gift, loan, money, or thing of value to an individual or business entity that provides services to an ERISA plan with the intent to influence the recipient's actions, decisions, or other duties relating to any question or matter concerning the plan. Section 1954 likewise prohibits an individual or business entity that provides services to an

ERISA plan from accepting such payments. Plaintiffs' health plans are employee welfare benefit plans governed by ERISA.

542. Plaintiffs and Class members are "persons" as defined in 18 U.S.C. § 1961(3) and as used in 18 U.S.C. § 1964(c), have been injured in their business or property by paying artificially inflated costs for fumarate drugs, and assert this count for relief pursuant to 18 U.S.C. § 1964(c).

543. Biogen's and the Co-Conspirator PBMs' illegal conduct directly targeted Plaintiffs and other health plans. In violation of Section 1954, Biogen made payments to each of the Co-Conspirator PBMs with the intent to influence those PBMs with respect to the formulary management services that the PBMs provide to Plaintiffs and other health plans. In making those illegal payments, Biogen knew that the Co-Conspirator PBMs made formulary decisions for their health plan clients or, at a minimum, had significant influence over their health plan clients' formulary decisions.

544. Plaintiffs and the health plans in the Classes are the first non-conspiring buyers in the supply chain affected and injured by the RICO violation described in this Count. Section 1954 specifically addresses bribes, kickbacks, and other conflict-of-interest payments to service providers for ERISA plans like Plaintiffs' and other Class members' health plans. Here, Biogen bribed the Co-Conspirator PBMs to influence and corrupt the services that the Co-Conspirator PBMs provide to Plaintiffs and Class members' health plans, not other entities in the prescription drug supply chain. In exchange for those bribes from Biogen, the PBM Co-Conspirators structured the formularies for Plaintiffs and their other health plan clients to suppress the adoption of low-cost generic Tecfidera over high-cost Tecfidera and Vumerity. Had Biogen not paid those bribes, the Co-Conspirator PBMs would have structured Plaintiffs' and Class members' formularies to promote the use of generic Tecfidera over Tecfidera and Vumerity.

545. Specifically, absent Biogen's bribes, the Co-Conspirator PBMs would not have placed generic Tecfidera on the same tier as Tecfidera and Vumerity on their formularies; the Co-Conspirator PBMs' formularies would not have placed step edits and prior authorizations on patients' use of generic Tecfidera; and the Co-Conspirator PBMs would not have designated generic Tecfidera as a specialty drug.

546. Those formulary actions directly and proximately caused Plaintiffs and Class members to pay more for fumarate drugs than they otherwise would. First, Plaintiffs and Class members bought more high-cost Tecfidera and Vumerity than they would have if Biogen had not bribed the Co-Conspirator PBMs to suppress the use of generic Tecfidera. Second, Biogen was able to charge higher prices for Tecfidera and Vumerity because Biogen insulated itself from generic competition by paying the Co-Conspirator PBMs to suppress the use of generic Tecfidera. Third, Biogen's payments to the Co-Conspirator PBMs for "parity" treatment caused the Co-Conspirator PBMs to put generic Tecfidera on the higher-priced specialty drug tier for those formularies that had such a tier. Absent Biogen's bribes, the Co-Conspirator PBMs would not have designated generic Tecfidera as a specialty drug on their formularies. Indeed, the fact that the Co-Conspirator PBMs did not treat generic Tecfidera as a specialty drug on all their formularies shows that there is no objective or inherent characteristic of generic Tecfidera that requires generic Tecfidera to be treated as a specialty drug.

547. Moreover, Plaintiffs and Class members directly purchased Tecfidera, Vumerity, and generic Tecfidera from specialty pharmacies that were owned or controlled by the Co-Conspirator PBMs. Biogen sold Tecfidera and Vumerity directly to the Co-Conspirator PBMs' specialty pharmacies.

A. The Biogen-PBM Pricing Enterprises.

548. Under 18 U.S.C. § 1961(4), a RICO enterprise may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

549. The RICO enterprises are associations-in-fact consisting of: (i) Biogen, including its directors, employees, and agents; and (ii) one of the five PBM Co-Conspirators, including the PBM's directors, employees, and agents. Those five association-in-fact enterprises (Biogen-Express Scripts, Biogen-CVS Caremark, Biogen-Optum Rx, Biogen-HPS, and Biogen-MHS) are collectively referred to as the "Biogen-PBM Pricing Enterprises."

550. Each Biogen-PBM Pricing Enterprise is, under RICO, an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, promoting, recommending for purchase, and administering prescriptions for Tecfidera and Vumerity, and deriving secret profits from those activities through the bribery and kickback scheme described in this Complaint. Those secret profits are greater than either Biogen or the Co-Conspirator PBMs could obtain absent the bribes and kickbacks misleadingly labeled as "rebates" or "fees" from Biogen to the Co-Conspirator PBMs.

551. As part of and to accomplish the common purpose of the respective Biogen-PBM Pricing Enterprises, Biogen systematically paid bribes and kickbacks—falsely labeled as rebates, administrative fees, or other payments—to the Co-Conspirator PBMs in exchange for those PBMs not favoring generic Tecfidera over Tecfidera and Vumerity on their formularies. Biogen's bribes and kickbacks likewise resulted in the Co-Conspirator PBMs baselessly designating generic Tecfidera as a specialty drug on some formularies. Biogen acted willfully, knowing that its

payments to the PBMs in exchange for not favoring generic Tecfidera would lead to the PBMs' health plan clients buying substantially more high-cost Tecfidera and Vumerity instead of low-cost generic Tecfidera, and paying more for generic Tecfidera.

552. Each Biogen-PBM Pricing Enterprise involved coordinated efforts between Biogen and the Co-Conspirator PBM, and neither Biogen nor the PBM could achieve the enterprise's goals on its own. But for the Biogen-PBM Pricing Enterprises' common purpose of deriving secret profits from their bribery and kickback schemes, the Co-Conspirator PBMs would have used their control over the management and administration of their health plan clients' formularies to promote the use of the substantially lower-cost generic Tecfidera at the expense of Tecfidera and Vumerity. The Co-Conspirator PBMs readily participated in the schemes so that they could receive Biogen's bribes, kickbacks, or other payments.

553. Biogen would not have paid those bribes, kickbacks, and other payments to the Co-Conspirator PBMs absent the Co-Conspirator PBMs insulating Tecfidera and Vumerity from generic competition. Biogen could not achieve the enterprises' goals on its own because Biogen could not ensure that Tecfidera and Vumerity would be insulated from generic competition absent its enterprise with each of the Co-Conspirator PBMs. Biogen could not manipulate the formularies of Plaintiffs and other health plans to suppress the use of generic Tecfidera without the assistance of the Co-Conspirator PBMs.

554. The bribery scheme that corrupted each Biogen-PBM Pricing Enterprise was mutually beneficial to Biogen and the Co-Conspirator PBM. Biogen benefitted because the PBMs took actions, such as formulary placement decisions, that suppressed competition from generic Tecfidera, which resulted in more profits to Biogen from sales of Tecfidera and Vumerity. The PBM in each Biogen-PBM Pricing Enterpise benefitted because Biogen paid the PBM to take

those anticompetitive actions. And as Biogen made more profits off its sales of Tecfidera and Vumerity, it could enhance the payments to the PBM in exchange for continuing or instituting new actions to suppress competition from generic Tecfidera. The bribery scheme gave Biogen and the PBM in each Biogen-PBM Pricing Enterprise an aligned profit motive and common purpose

555. Each of the Biogen-PBM Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Biogen and the Co-Conspirator PBM in each RICO enterprise. As to each of the Biogen-PBM Pricing Enterprises, there is a common communication network by which Biogen and the Co-Conspirator PBM regularly share information, including information regarding Tecfidera and Vumerity distribution and pricing.

556. In order to effectuate the schemes, Biogen and each Co-Conspirator PBM met or communicated on a regular basis to discuss Tecfidera and Vumerity prices, formulary position, rebates or administrative fees, other monies paid by Biogen to the Co-Conspirator PBM, what the PBM had to do for Biogen to pay those monies to the PBM, and coordination of all of the above.

557. Further, the common communication network between Biogen and each Co-Conspirator PBM effectuated the purpose of implementing the bribery and kickback schemes and the exchange of financial rewards for the PBM activities that benefitted—and continue to benefit—Biogen and the PBMs at the expense of Plaintiffs and the PBMs' other health plan clients.

558. Each of the Biogen-PBM Pricing Enterprises functions as a continuing unit and has been operated for the purposes of carrying out the bribery and kickback scheme and its concealment. In addition, each of the Biogen-PBM Pricing Enterprises existed for years, such that each enterprise had longevity sufficient for its associates to pursue the enterprise's purpose.

559. At all relevant times, each Biogen-PBM Pricing Enterprise had an existence separate and distinct from that of its members. Biogen and each of Express Scripts, CVS Caremark, Optum Rx, HPS, and MHS are distinct corporate entities.

560. Each member of the respective RICO enterprises also has an ascertainable structure distinct from the pattern of racketeering activities of the RICO enterprise. Biogen pays the Co-Conspirator PBMs administrative fees for services not directly related to the bribery and kickback payments alleged in this Complaint. Moreover, Biogen and the Co-Conspirator PBMs had legitimate business negotiations about the formulary placement of Tecfidera before the introduction of generic Tecfidera, which led to the bribery and kickback scheme. And if the bribery and kickback scheme were discontinued, Biogen and the Co-Conspirator PBMs would revert to the legitimate business negotiations to determine whether Tecfidera and Vumerity would be covered under the PBMs' formularies.

561. At all relevant times, Biogen and each Co-Conspirator PBM knowingly, purposefully, and willingly engaged and participated in the bribery and kickback scheme through each Biogen-PBM Pricing Enterprise and reaped substantial profits from that scheme.

562. Biogen and the Co-Conspirator PBMs were each willing participants in their respective Biogen-PBM Pricing Enterprises, had a common and unlawful purpose and interest in the objective of the bribery and kickback schemes of the respective enterprises, and functioned within a structure designed to effectuate those enterprises' purposes, i.e., to increase profits for Biogen and the Co-Conspirator PBMs.

B. Interstate Commerce

563. Each of the Biogen-PBM Pricing Enterprises engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the sale,

promotion, and recommendation for purchase of Tecfidera and Vumerity; the negotiation of formulary placement for Tecfidera and Vumerity, including the formulary placement of Tecfidera and Vumerity relative to generic Tecfidera; the negotiation of contracts regarding Tecfidera and Vumerity; and the payment of rebates, fees, or other money related to the purchase, use, and formulary placement of Tecfidera and Vumerity.

564. Moreover, the Biogen-PBM Pricing Enterprises' bribery scheme affected formularies covering millions of ERISA health plan participants throughout the United States. Consequently, the Biogen-PBM Pricing Enterprises affected: the volume of Tecfidera and Vumerity sold to ERISA plans throughout the United States; the volume of generic Tecfidera sold to ERISA plans throughout the United States; the amounts paid for fumarate drugs by ERISA plans throughout the United States.

565. The illegal conduct by Biogen and each Co-Conspirator PBM as part of and in furtherance of the Biogen-PBM Pricing Enterprises were carried out by employees of Biogen and Co-Conspirator PBMs, working across state boundaries, who frequently transferred documents, information, and funds through interstate wire facilities. Indeed, Biogen and each Co-Conspirator PBM are headquartered in different states. Biogen is headquartered in Massachusetts. Express Scripts is headquartered in Missouri. CVS Caremark is headquartered in Rhode Island. Optum Rx is headquartered in Minnesota. HPS is headquartered in Kentucky. MHS is headquartered in California.

C. Conduct of the RICO Enterprises' Affairs

566. Biogen and the Co-Conspirator PBMs have acted in concert to corrupt what was previously a legitimate business relationship between Biogen and each of the PBMs.

567. Biogen has exerted control over each Biogen-PBM Pricing Enterprise by providing bribes and kickbacks, labeled as rebates, administrative fees, or other payments, to induce the Co-Conspirator PBMs not to favor generic Tecfidera over Tecfidera and Vumerity on the PBMs' formularies and to improperly designate generic Tecfidera as a specialty drug. In so doing, Biogen participated in the operation and the management of the enterprise itself and asserted some control over the enterprise.

568. Each Co-Conspirator PBM has exerted control over each Biogen-PBM Enterprise by soliciting and obtaining bribes and kickbacks, labeled as rebates, administrative fees or other payments, in exchange for not favoring generic Tecfidera over Tecfidera and Vumerity on the PBMs' formularies and for improperly designating generic Tecfidera as a specialty drug. In so doing, each Co-Conspirator PBM participated in the operation and the management of the enterprise itself and asserted some control over the enterprise.

569. The Biogen-PBM Pricing Enterprises were not run-of-the-mill commercial relationships. Neither Biogen nor the PBMs alone had the capability and the economic incentive to suppress competition from generic Tecfidera; coordination between Biogen and the PBM in each Biogen-PBM Pricing Enterprise was essential to the scheme's success. Therefore, each of Biogen and the PBMs have been economically interdependent for the purposes of the enterprises. Indeed, as part of the Biogen-PBM Pricing Enterprises, Biogen involved itself in each PBM's affairs by conditioning payments on the PBM making formulary decisions to suppress generic competition, which the PBM would not have done absent Biogen's payments. Further, Biogen and the PBM in each of the Biogen-PBM Pricing Enterprises shared the profits generated by the scheme to suppress competition from generic Tecfidera: Biogen profited by charging higher prices and selling more Tecfidera and Vumerity than it otherwise would, which contributed to Biogen's

bribe payments to the PBMs in each RICO enterprise. Accordingly, the conduct described here involved a shared goal and concerted activity between Biogen and the PBM in each of the Biogen-PBM Pricing Enterprises. Biogen and the PBMs were not acting in their individual capacities to advance their individual self-interests.

D. Pattern of Racketeering Activity: Violations of 18 U.S.C. § 1954(4)

570. The Co-Conspirator PBMs provide benefit plan services to ERISA plans, including Plaintiffs and Class members. Because of their expertise in creating formularies and negotiating with prescription drug manufacturers, the Co-Conspirator PBMs have significant influence over their ERISA plan clients' decisions regarding prescription drug coverage.

571. Under Section 1954, it is unlawful to directly or indirectly give or offer such a fee, kickback, commission, gift, loan, money, or thing of value to an individual or business entity that provides services to an ERISA plan with the intent to influence the recipient's actions, decisions, or other duties relating to any question or matter concerning the plan.

572. Biogen violated Section 1954 every time that it made a payment to a Co-Conspirator PBM with the intent to influence the PBMs not to prefer lower-cost generic Tecfidera over higher-cost Tecfidera and Vumerity on the PBMs' formularies. Those Biogen payments to the Co-Conspirator PBMs were illegal under Section 1954 regardless of whether Biogen or the Co-Conspirator PBMs called those payments "rebates," "fees," or any other name. Further, the Biogen payments to the Co-Conspirator PBMs were illegal under Section 1954 because Biogen made those payments, however labeled, with the intent to influence the PBMs to designate generic Tecfidera as a specialty drug.

573. Likewise, under Section 1954, it is unlawful for an individual or business entity that provides services to an ERISA plan to receive or agree to receive any fee, kickback,

commission, gift, loan, money, or thing of value because of or with intent to be influenced with respect to any of the actions, decisions, or other duties relating to any question or matter concerning the plan.

574. Each Co-Conspirator PBM violated Section 1954 every time that the PBM received a payment from Biogen with the intent to be influenced with respect to its actions, decisions, or other duties relating to ERISA plans, such that the PBM would not prefer lower-cost generic Tecfidera over higher-cost Tecfidera and Vumerity on the PBM's formularies. Each Co-Conspirator PBM's receipt of Biogen's payments was illegal regardless of whether Biogen or the Co-Conspirator PBMs called those payments "rebates," "fees," or any other name. Further, each Co-Conspirator PBM's receipt of Biogen's payments was illegal under Section 1954 because Biogen made those payments, however labeled, with the intent to influence the PBM to designate generic Tecfidera as a specialty drug, and each PBM accepted such payments with the intent to be so influenced.

575. The conduct of each Biogen-PBM Pricing Enterprise involved at least two related acts that violated Section 1954 by Biogen to the Co-Conspirator PBM.

576. The payments described in this Complaint were not bona fide salaries, compensation, or other payments made to the Co-Conspirator PBMs for services actually performed in the regular course of their duties as an organization providing benefit plan services to ERISA plans. The Co-Conspirator PBMs did not provide a legitimate service to Biogen that justified the payments. Moreover, the Co-Conspirator PBMs' ordinary course of duties in providing benefit plan services to ERISA plans does not involve soliciting or accepting manufacturer payments for the purpose of taking actions that benefit manufacturers and the PBMs at the expense of the PBMs' ERISA plan clients. (See Section V(A) above, listing examples of

Co-Conspirator PBM public statements regarding their aligning interests with health plan clients, lowering health plans' costs, and using formularies to promote low-cost generic alternatives to high-cost branded drugs.)

577. Further, neither Biogen nor the Co-Conspirator PBMs disclosed the payments described in this Complaint, or the purpose or amounts of those payments, to the PBMs' ERISA plan clients. Instead, the Biogen-PBM Pricing Enterprises intentionally mislabeled Biogen's bribe payments as "fees," as "rebates," or with some other label to conceal their true illicit purpose. The Biogen-PBM Pricing Enterprises also used rebate aggregators to avoid disclosing the illegal payments to the Co-Conspirator PBMs' ERISA plan clients.

E. Harm Proximately Caused by the Racketeering Activity.

578. Congress enacted Section 1954 specifically to protect ERISA plans like Plaintiffs and Class members from bribe and kickback schemes. Plaintiffs' and Class members' ERISA plans are the most direct and immediate victims of the racketeering activity, which involved Biogen bribing the PBM Co-Conspirators to make formulary and specialty designation decisions that raised the prescription drug costs for Plaintiffs and Class members, which was the opposite of what Plaintiffs and Class members hired those PBMs to do.

579. Biogen paid bribes and kickbacks to the Co-Conspirator PBMs in exchange for the PBMs not favoring generic Tecfidera on their respective formularies. Biogen paid those bribes and kickbacks to maintain or increase Biogen's sales and profits. The Co-Conspirator PBMs accepted those bribes and kickbacks to increase their profits. Biogen and each of the Co-Conspirator PBMs intended and foresaw that their racketeering activity would cause Plaintiffs and Class members to pay substantial overcharges on fumarate products.

580. Though the Co-Conspirator PBMs could have used their control over the development, management, and administration of their formularies to lower their clients' costs for purchasing fumarate products, the Co-Conspirator PBMs instead leveraged their respective positions to solicit and obtain Biogen's bribes and kickbacks for their own financial benefit. In doing so, the Co-Conspirator PBMs acted contrary to the interests of their ERISA plan clients, who retained and trusted the Co-Conspirator PBMs to lower their prescription drug costs, not raise them.

581. Rather than lower the price of Tecfidera and Vumerity to the price of generic Tecfidera to obtain the typical "Tier One" formulary placement for low-cost generic drugs, Biogen instead engaged in schemes with the Co-Conspirator PBMs to corrupt the PBMs' normal practice of using formularies to promote the use of low-cost generics over high-cost branded drugs. Instead, Biogen's schemes with the Co-Conspirator PBMs involved Biogen paying the PBMs not to favor generic Tecfidera over the substantially higher-cost Tecfidera and Vumerity on the PBMs' formularies. Those schemes allowed Biogen and the Co-Conspirator PBMs to profit at the expense of Plaintiffs and Class members.

582. Absent the payment of bribes and kickbacks, Biogen would have been forced to compete for preferred formulary placement through lower prices, as would occur in a legitimate, uncorrupted market. As the gatekeepers in the supply chain, the Co-Conspirator PBMs could and would have used formulary placement or exclusion to penalize Biogen if it charged substantially higher prices for Tecfidera and Vumerity than the price of generic Tecfidera.

583. Accordingly, the bribery scheme that corrupted each of the Biogen-PBM Pricing Enterprises was specifically designed to influence and manipulate Plaintiffs' and other health plans' formularies to the detriment of those ERISA plans. Because the bribery scheme targeted

health plan formularies, Plaintiffs' and Class members' ERISA plans were direct targets of the RICO violation described here.

584. Biogen's and the Co-Conspirator PBMs' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and Class members to be injured in their business or property. First, the Biogen-PBM Pricing Enterprises led to Plaintiffs and Class members purchasing significantly more high-cost Tecfidera and Vumerity than low-cost generic Tecfidera than would have otherwise occurred absent Biogen's and the Co-Conspirator PBMs' illegal conduct. Second, by suppressing the effectiveness of generic Tecfidera as a competitive alternative to Tecfidera and Vumerity, Biogen successfully charged higher prices for Tecfidera and Vumerity than it otherwise could have in a competitive market. Third, the Biogen-PBM Pricing Enterprises resulted in the Co-Conspirator PBMs designating generic Tecfidera as a specialty drug on the Co-Conspirator PBMs' formularies even though the specialty designation was unjustified. Based on those baseless specialty designations, Plaintiffs and Class members paid artificially inflated markups for generic Tecfidera that in some instances exceeded 2,000% over the pharmacy's acquisition cost.

585. Plaintiffs and Class members have incurred, and continue to incur, substantial overcharges on fumarate products as a direct result of the Biogen-PBM Pricing Enterprises' racketeering activity.

586. Plaintiffs and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries to their business or property they suffered as a result of the Biogen-PBM Pricing Enterprises' racketeering activity.

CLAIM SEVEN
CONTRACTS IN RESTRAINT OF TRADE UNDER STATE LAW

587. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

588. Biogen entered into agreements with each of the five PBMs pursuant to which it agreed to pay, and did pay, substantial kickbacks to each of them in exchange for each of their reciprocal agreement to disadvantage generic Tecfidera on their formularies and/or to limit distribution of generic Tecfidera to specialty pharmacies. Biogen made each of the agreements with the purpose and effect of impairing generic competition and buying time for Biogen to switch the market from Tecfidera to Vumerity. When entering into the agreements, each of the five PBMs knew and understood Biogen's intent and the agreements' likely effect.

589. The purpose and effect of Biogen's payments to the five PBMs under the agreements was to substantially impair competition from generic Tecfidera. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effects. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

590. The agreements, individually and collectively, covered a sufficiently substantial percentage of the relevant commerce to harm competition.

591. As a direct and proximate result of Biogen's unlawful restraint of trade, Plaintiffs and Class members paid artificially inflated prices for fumarate and were harmed as a result.

592. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Ca. Bus. & Prof. §§ 16700, 17200, *et seq*., with respect to purchase of fumarate in California by class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

d. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.1, *et seq*., with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

h. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

i. Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchase of fumarate in Massachusetts by class members and/or purchases by Massachusetts residents.

j. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

k. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by class members and/or purchases by Maryland residents.

l. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

o. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

p. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

q. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

r. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

u. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchase of fumarate in New York by class members and/or purchases by New York residents.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

w. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

bb. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

cc. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

593. Plaintiffs and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

594. Plaintiffs and the Classes seek damages, multiple damages, and other relief as permitted by law.

CLAIM EIGHT
MONOPOLIZATION
UNDER STATE LAW

595. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

596. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

597. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate by switching the market from Tecfidera to Vumerity through coercive means. Biogen's anticompetitive scheme included, cumulatively and in the alternative:

(a) concocting the false claim that Vumerity is medically superior to Tecfidera;

(b) pervasively marketing the false claim that Vumerity is medically superior to Tecfidera;

(c) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Vumerity;

(d) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which Vumerity is subject;

(e) providing patient coupons to insureds, with the purpose and effect of eliminating accurate price signals as to the relative costs of Vumerity and generic Tecfidera;

(f) linking rebates and fees on Tecfidera to better formulary placement of Vumerity; and

(g) directly reducing the supply of generic Tecfidera.

598. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

599. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

600. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

601. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

602. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiffs and Class members.

603. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Ca. Bus. & Prof. §§ 16700, 17200, *et seq.*, with respect to purchase of fumarate in California by class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

d. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

h. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

i. Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchase of fumarate in Massachusetts by class members and/or purchases by Massachusetts residents.

j. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

k. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by class members and/or purchases by Maryland.

l. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

o. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

p. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

q. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

r. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

u. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchase of fumarate in New York by class members and/or purchases by New York residents.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

w. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

bb. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

cc. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

604. Plaintiffs and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

605. Plaintiffs and the Classes seek damages, multiple damages, and other relief as permitted by law.

CLAIM NINE
MONOPOLIZATION
UNDER STATE LAW

606. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

607. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

608. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate. Biogen's anticompetitive scheme included, cumulatively and in the alternative:

(a) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Tecfidera;

(b) paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies, compared to Vumerity;

(c) paying one or more of the five PBMs to limit distribution of generic Tecfidera to specialty pharmacies;

(d) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which branded Tecfidera is subject;

(e) paying one or more of the five PBMs to subject generic Tecfidera to the same (or worse) dispensing restrictions—including step edits and prior authorizations—to which Vumerity is subject;

(f) providing patient coupons to insureds, with the purpose and effect of eliminating accurate price signals as to the relative costs of Tecfidera and generic Tecfidera;

(g) providing patient coupons to insureds, with the purpose and effect of eliminating accurate price signals as to the relative costs of generic Tecfidera and Vumerity;

(h) anticompetitively switching prescriptions from Tecfidera to Vumerity through coercive anad unlawful means;

(i) concocting the false claim that Vumerity is medically superior to Tecfidera;

(j) pervasively marketing the false claim that Vumerity is medically superior to Tecfidera;

(k) linking rebates and fees on Tecfidera to better formulary placement of Vumerity; and

(l) directly reducing the supply of generic Tecfidera.

609. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

610. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

611. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

612. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

613. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiffs and Class members.

614. Plaintiffs and the Class members have been injured in their business or property as a direct and proximate result of Biogen's anticompetitive conduct, and their injuries are the type that the statutes were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

615. Plaintiffs and the Class members seek damages and treble damages as permitted by law for the injuries they suffered as a result of the Biogen's anticompetitive conduct.

616. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Ca. Bus. & Prof. §§ 16700, 17200, *et seq.*, with respect to purchase of fumarate in California by class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

d. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

h. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

i. Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchase of fumarate in Massachusetts by class members and/or purchases by Massachusetts residents.

j. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

k. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by class members and/or purchases by Maryland.

l. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

o. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

p. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

q. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

r. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

u. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchase of fumarate in New York by class members and/or purchases by New York residents.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

w. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

bb. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

cc. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

617. Plaintiffs and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

618. Plaintiffs and the Class seek damages, multiple damages, and other relief as permitted by law.

CLAIM TEN
CONSPIRACY TO MONOPOLIZE
UNDER STATE LAW

619. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

620. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

621. Biogen conspired with the PBMs and their specialty pharmacies to create and maintain a monopoly in the market for fumarate. Biogen and the PBMs and their specialty pharmacies engaged in anticompetitive conduct in furtherance of its conspiracy to maintain a monopoly, which included, cumulatively and in the alternative: (a) agreeing to pay and paying one or more of the five PBMs to disadvantage generic Tecfidera on their formularies and/or to limit distribution of generic Tecfidera to specialty pharmacies; (b) conspiring to switch the market from Tecfidera to Vumerity; and (c) entering into agreements that caused Plaintiffs and Class members

to be required to purchase Tecfidera, Vumerity and generic Tecfidera from the PBM-owned specialty pharmacies at supracompetitive prices; and (f) conspiring to impair generic competition and suppress sales of lower cost generic Tecfidera.

622. Through Biogen's conspiracy to monopolize, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiffs and Class members.

623. The goal, purpose and effect of the Biogen-directed conspiracy was and is to maintain and extend Biogen's monopoly over the relevant market by and through the anticompetitive conduct described above.

624. Biogen's conspiracy to monopolize harmed competition and purchasers as alleged above.

625. There are no non-pretextual procompetitive justifications for Biogen's conspiracy to monopolize. Even if there were such a conceivable justification, the conspiracy's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

626. Biogen's conspiracy to monopolize was the direct and proximate cause of the injuries to Plaintiffs and Class members.

627. Plaintiffs and the Class members have been injured in their business or property as a direct and proximate result of Biogen's conspiracy to monopolize, and their injuries are the type that the statutes were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

628. By engaging in the foregoing conduct, Biogen has intentionally and wrongfully conspired to monopolize in violation of the state laws alleged herein.

629. Plaintiffs and the Class members seek damages and treble damages as permitted by law for the injuries they suffered as a result of the Biogen's conspiracy to monopolize.

630. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Ca. Bus. & Prof. §§ 16700, 17200, *et seq.*, with respect to purchase of fumarate in California by class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

d. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

h. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

i. Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchase of fumarate in Massachusetts by class members and/or purchases by Massachusetts residents.

j. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

k. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by class members and/or purchases by Maryland.

l. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

o. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

p. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

q. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

r. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

u. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchase of fumarate in New York by class members and/or purchases by New York residents.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

w. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

bb. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

cc. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

631. Plaintiffs and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

632. Plaintiffs and the Classes seek damages, multiple damages, and other relief as permitted by law.

XX. DEMAND FOR JUDGMENT

633. WHEREFORE, Plaintiffs, on behalf of themselves and the Classes, demand judgment in their favor and respectfully requests that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes and declare the Plaintiffs as representatives of the Classes;

b. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, of Section 2(c) of the Robinson-Patman Act, of the Racketeer Influenced and Corrupt Organizations Act, of 18 U.S.C. § 1954(4), and of the other statutes set forth above;

c. Enter judgment against Biogen in favor of Plaintiffs and the Classes;

d. Grant Plaintiffs and the Classes equitable relief in the nature of disgorgement, restitution, the creation of a constructive trust, mandatory licenses, and other injunctive relief, to remedy Biogen's anticompetitive conduct;

e. Award the Classes damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

f. Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

g. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Biogen's unlawful conduct, and as the Court deems just.

XXI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs on behalf of themselves and the proposed Classes demand a trial by jury on all issues so triable.

Dated: August 20, 2025

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CERTIFICATE OF SERVICE

I certify that on August 20, 2025, I caused a true and correct copy of Plaintiffs' Consolidated Second Amended Class Action Complaint to be served on all counsel of record via the Court's CM/ECF system.

/s/ Steve D. Shadowen
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